

FIGURE 1

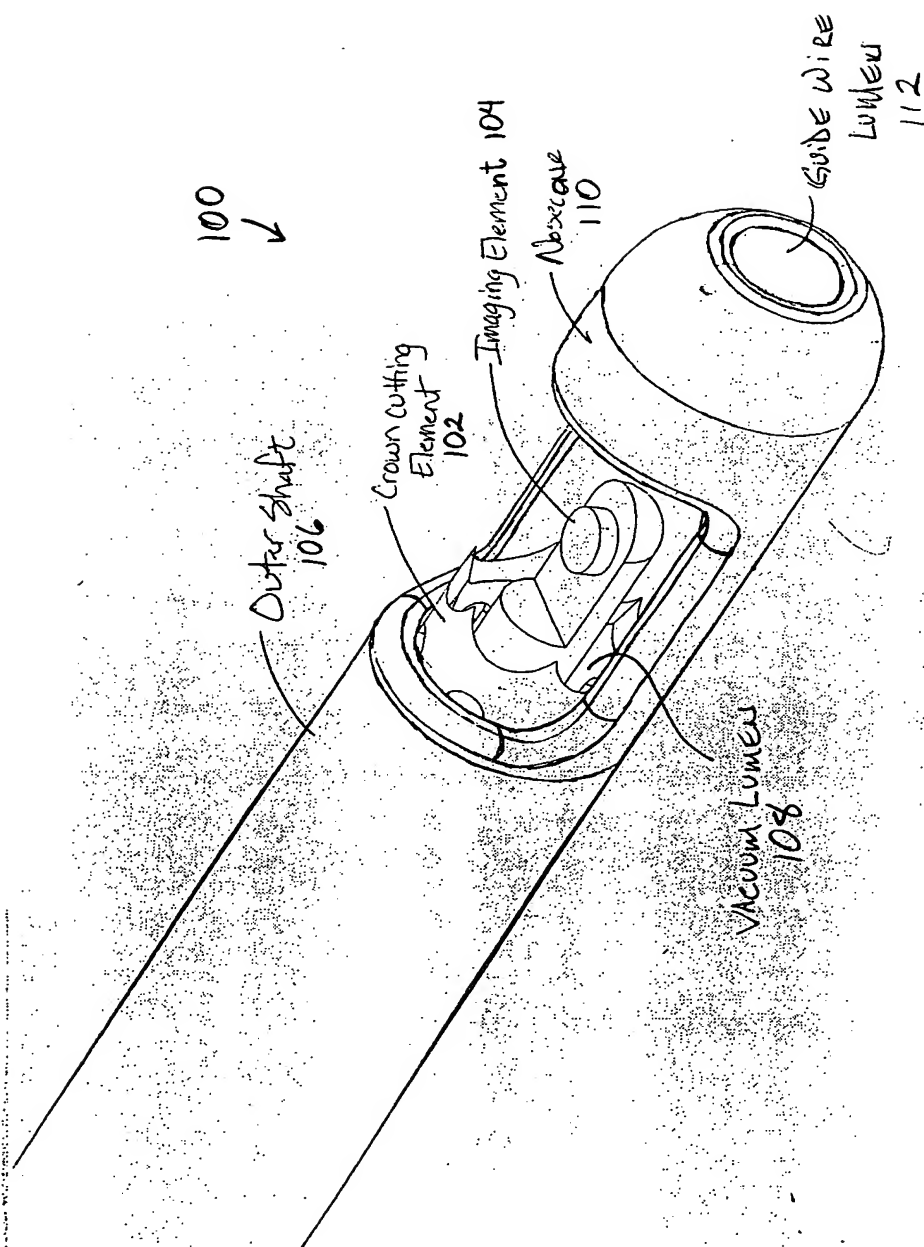


FIGURE 1

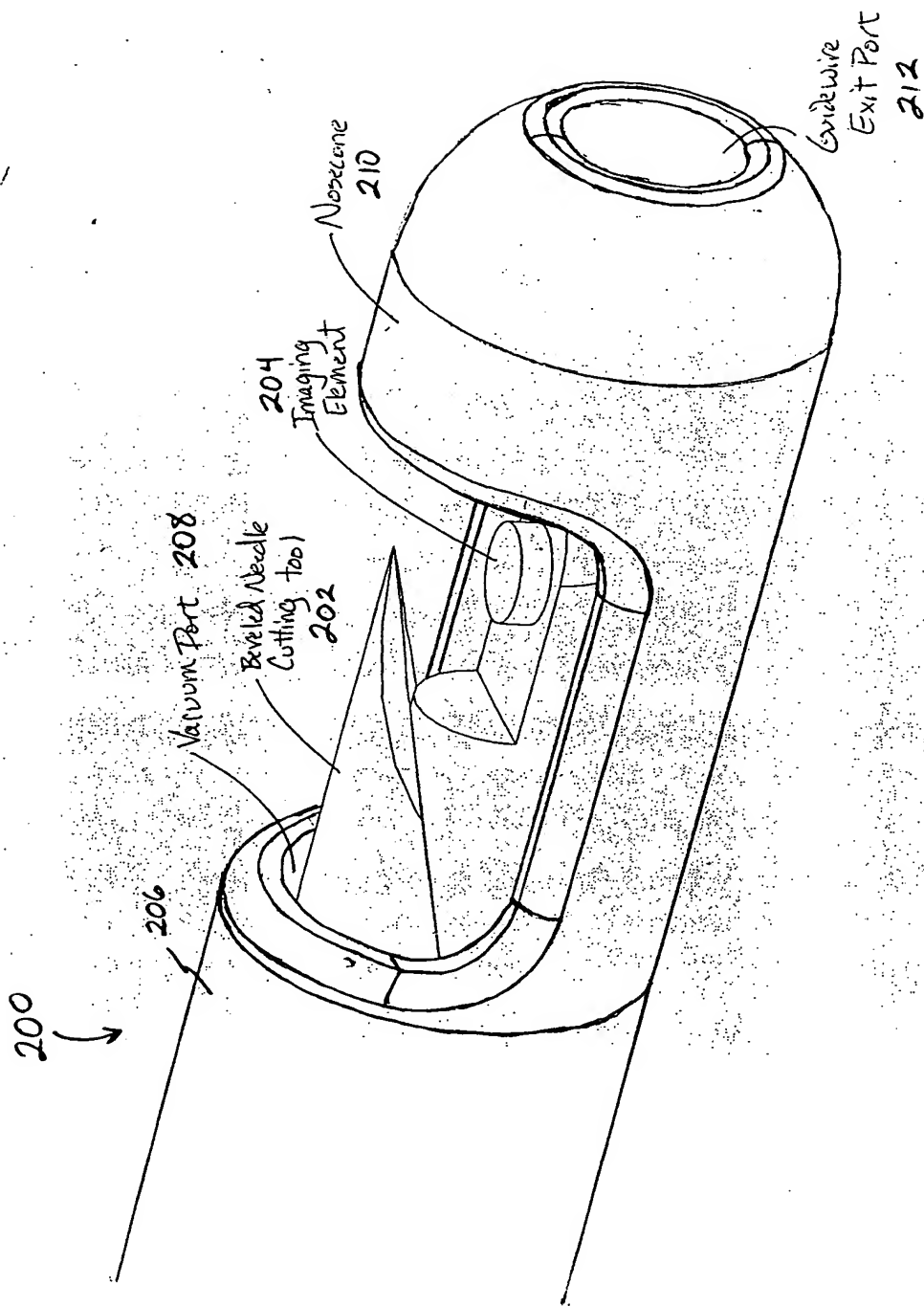


FIGURE 2

300
↓

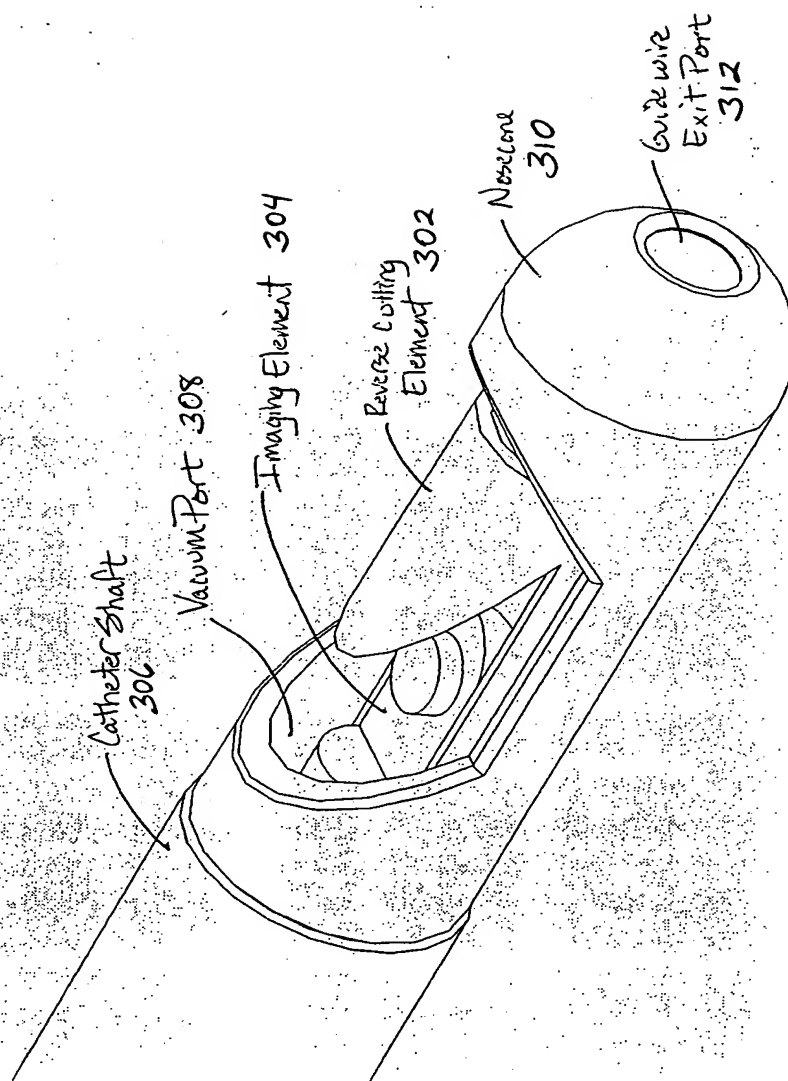


FIGURE 3

FIG. 4

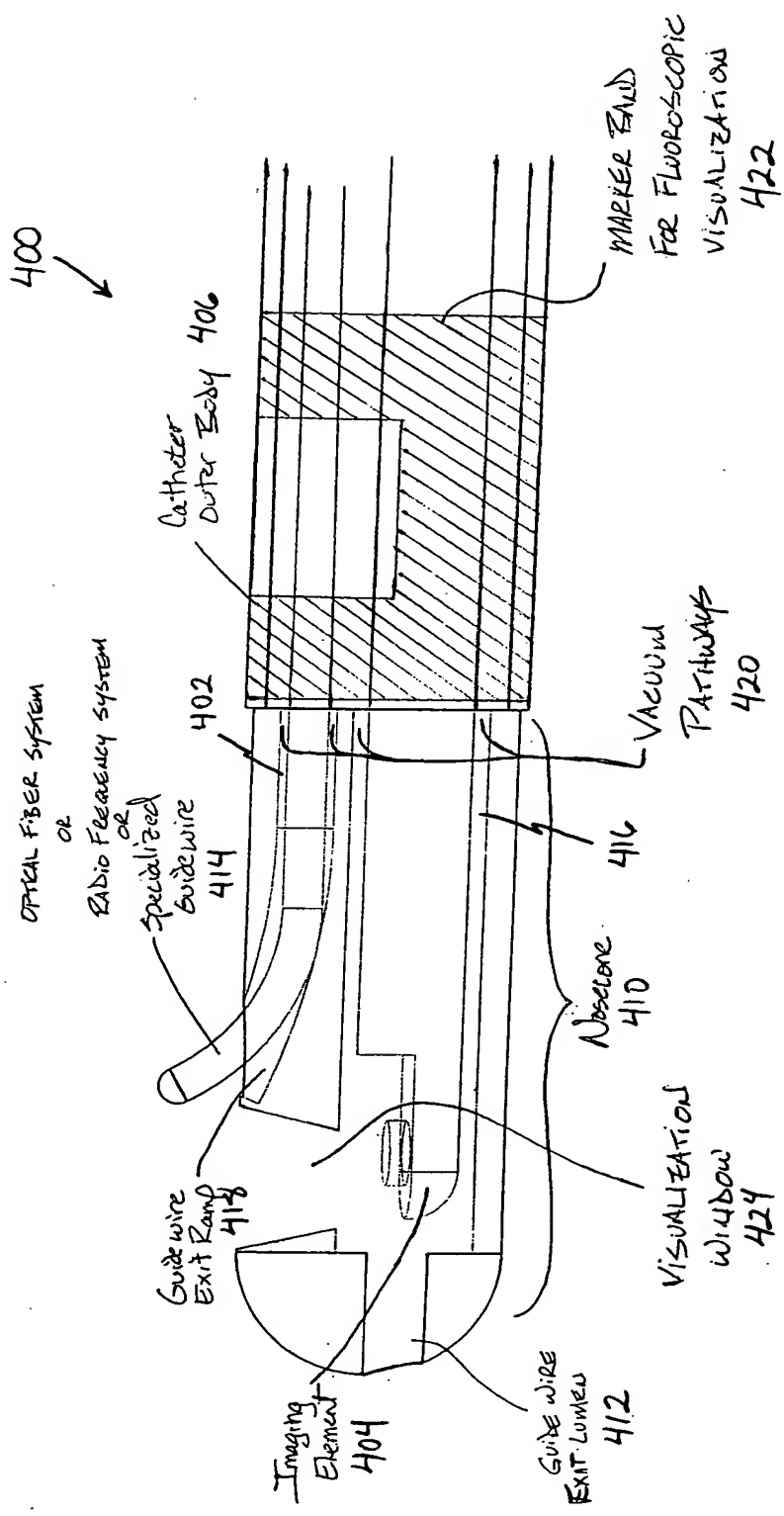


FIGURE 4

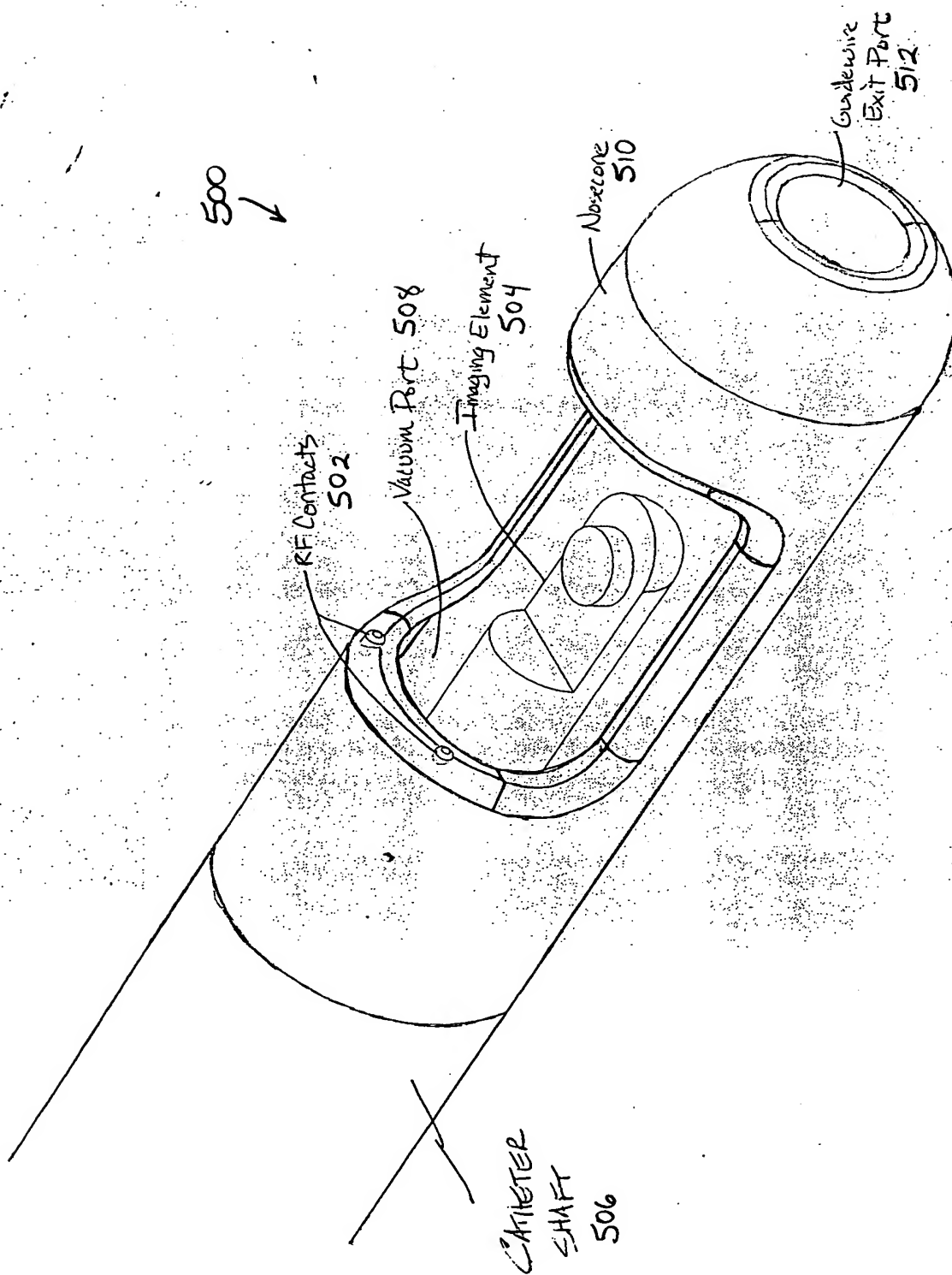


FIGURE 5

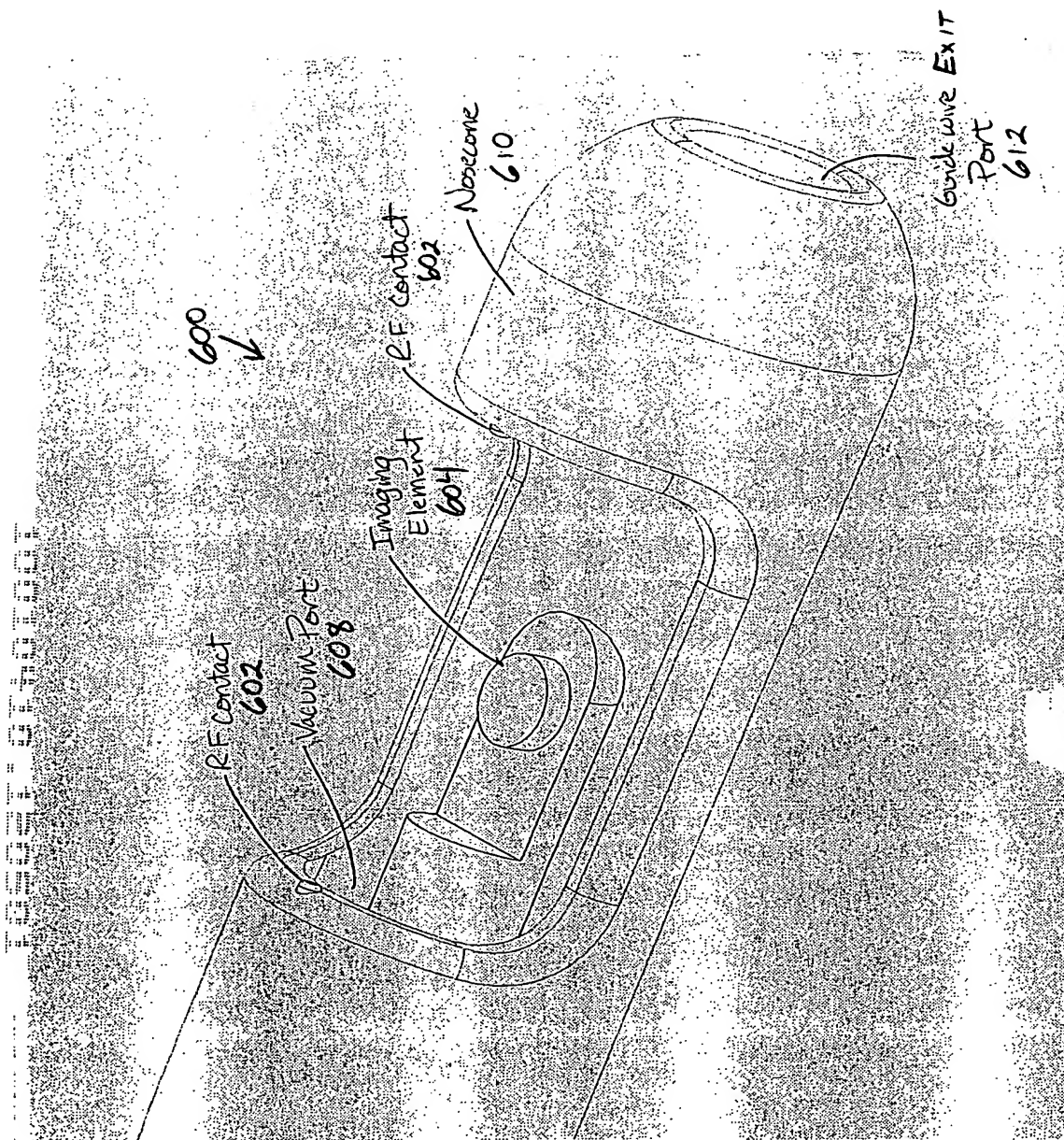


FIGURE 6

FIG. 7A

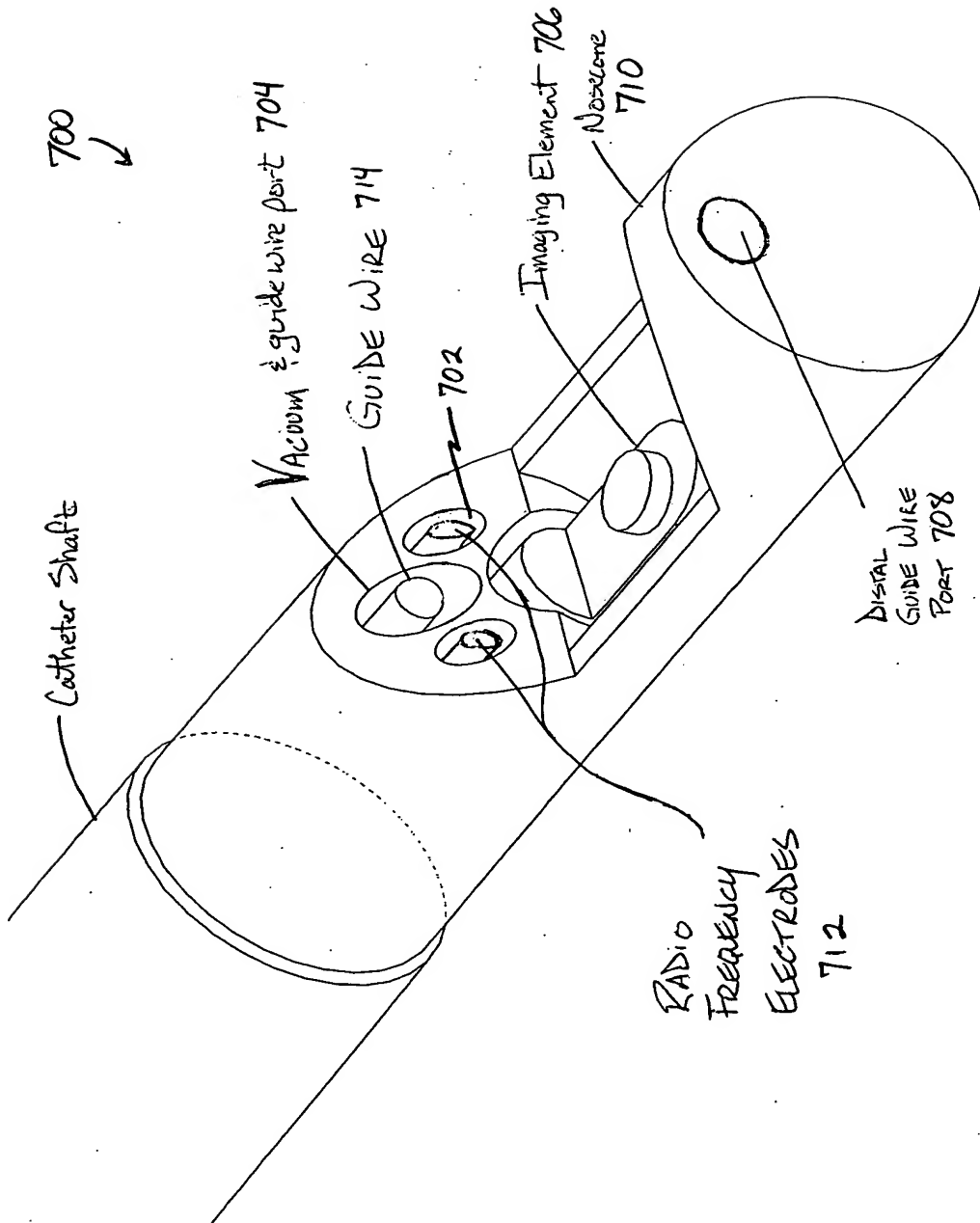


FIGURE 7A

FIG. 7B

750
↓

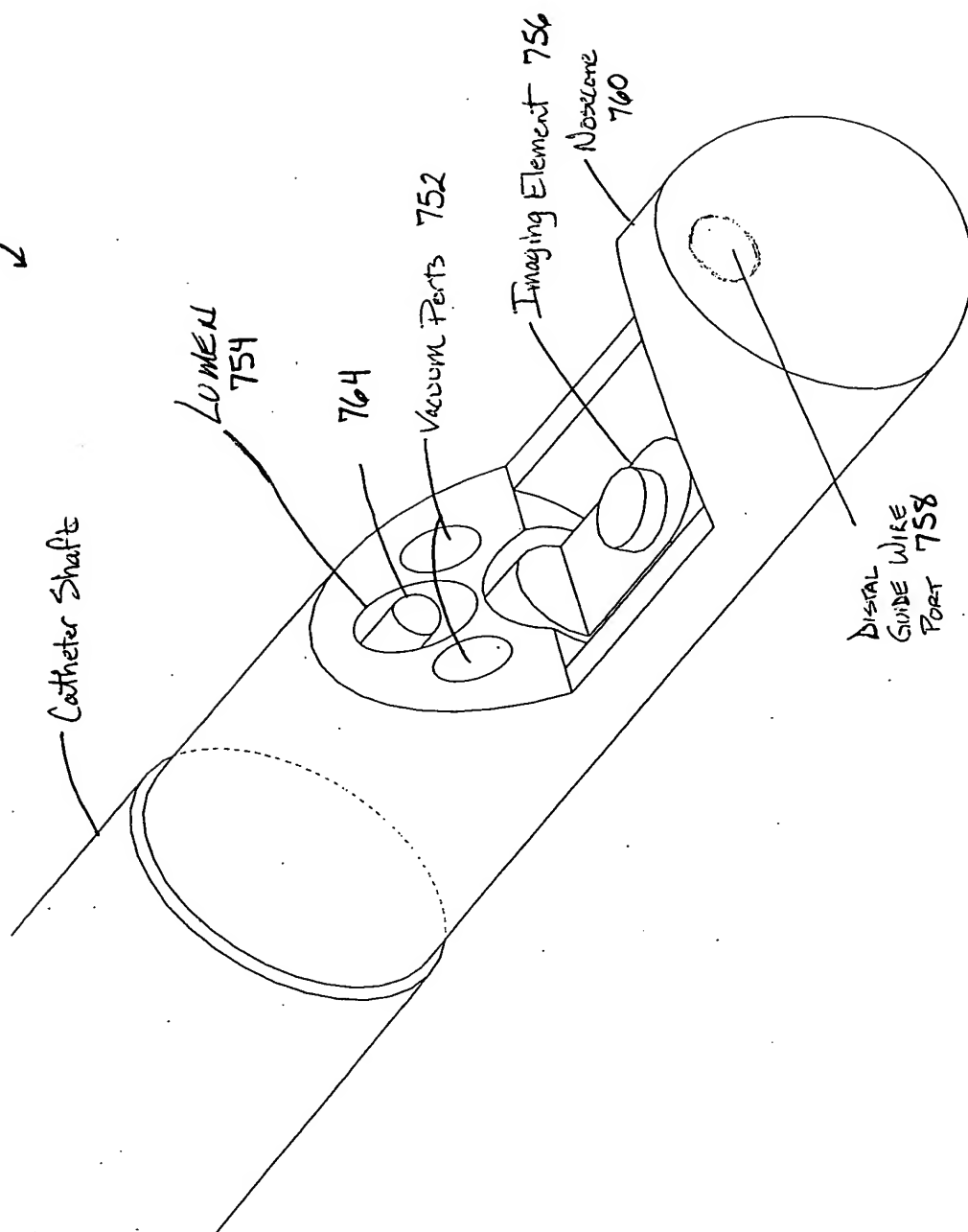


FIGURE 7B

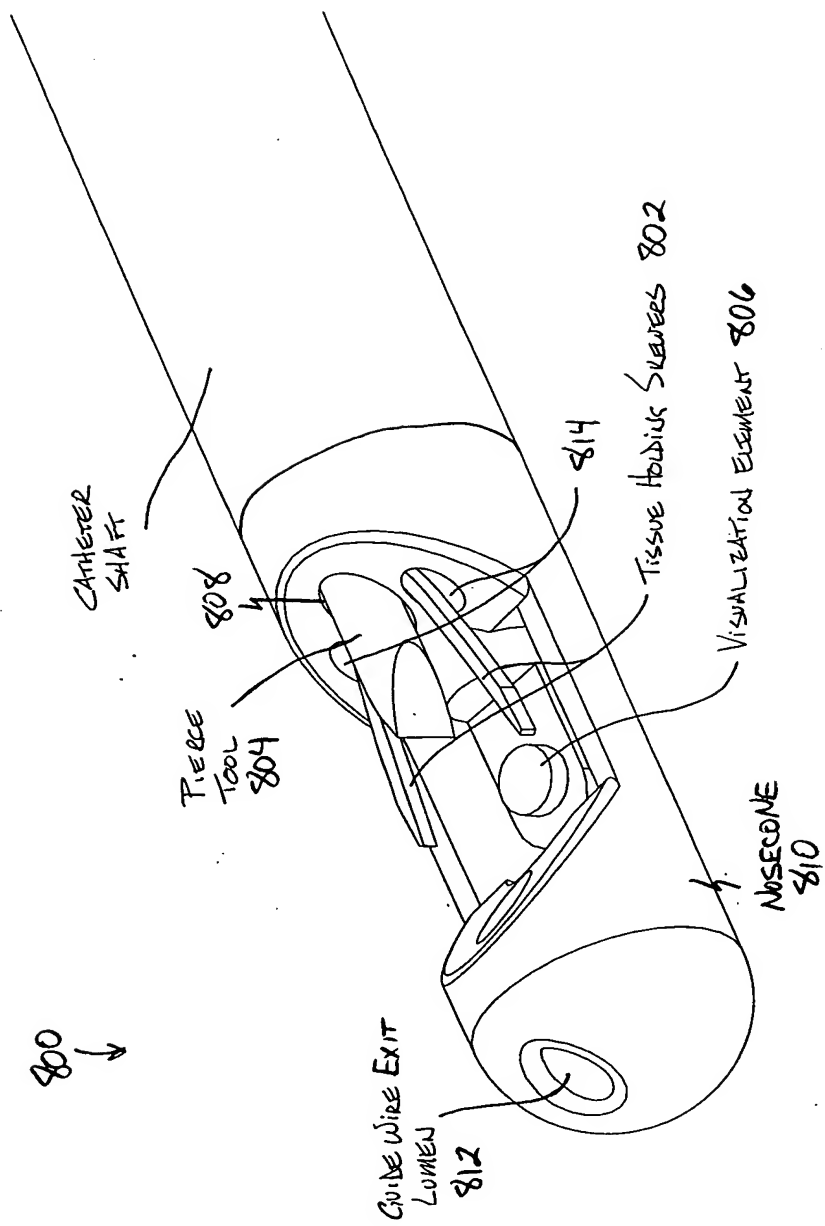


FIGURE 8

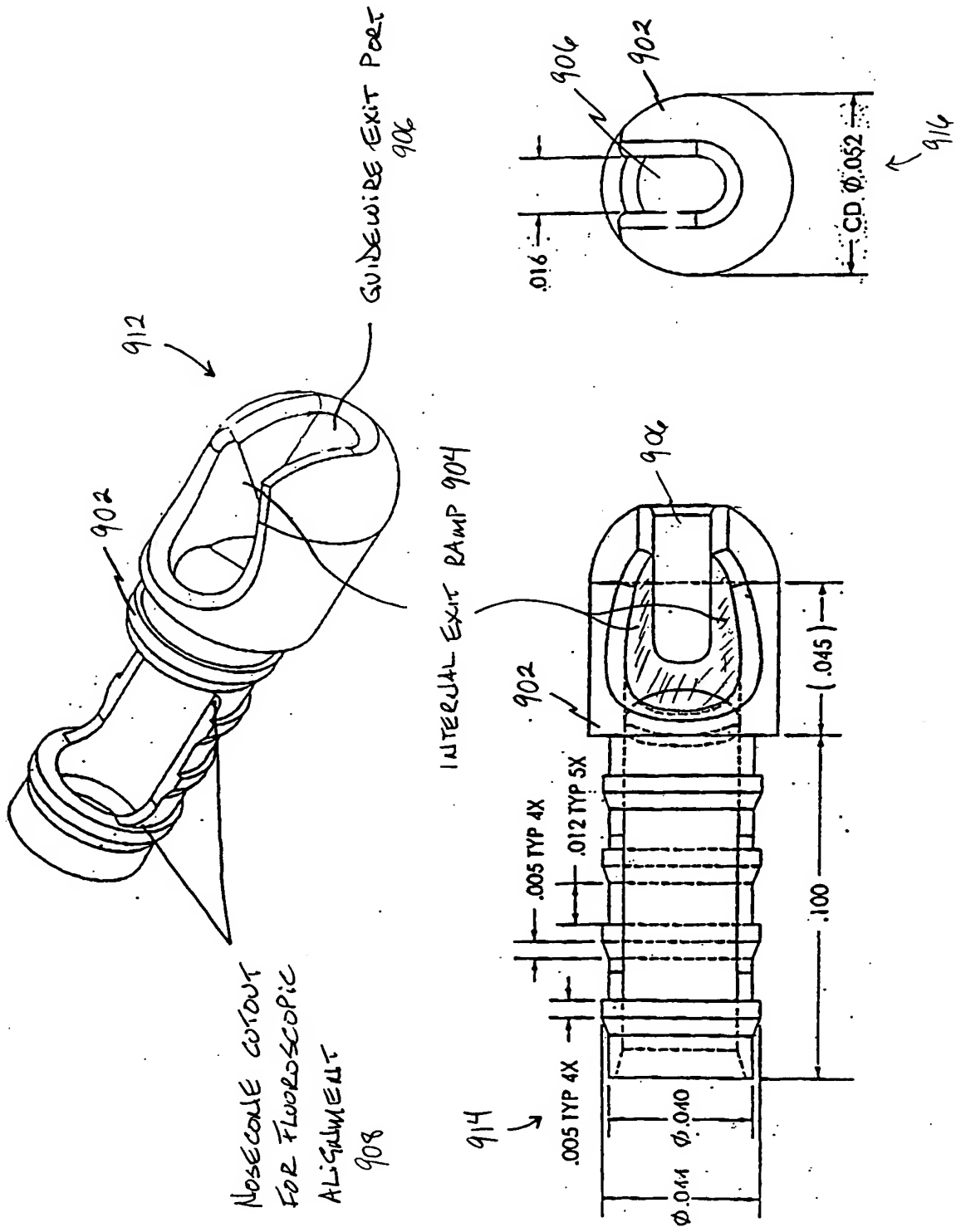


FIGURE 9A

950
VESSEL WALL →

VESSEL TRUE LUMEN 960

Sub-Optimal

Tissue 942

920

CATHETER SHAFT

Vessel Wall 950

930

RE-ENTRY
ELEMENTS
924

SUB. INTIMAL PLANE
940

902

INTERNAL EXIT RAMP 904

Figure 9b

FIG. 9C

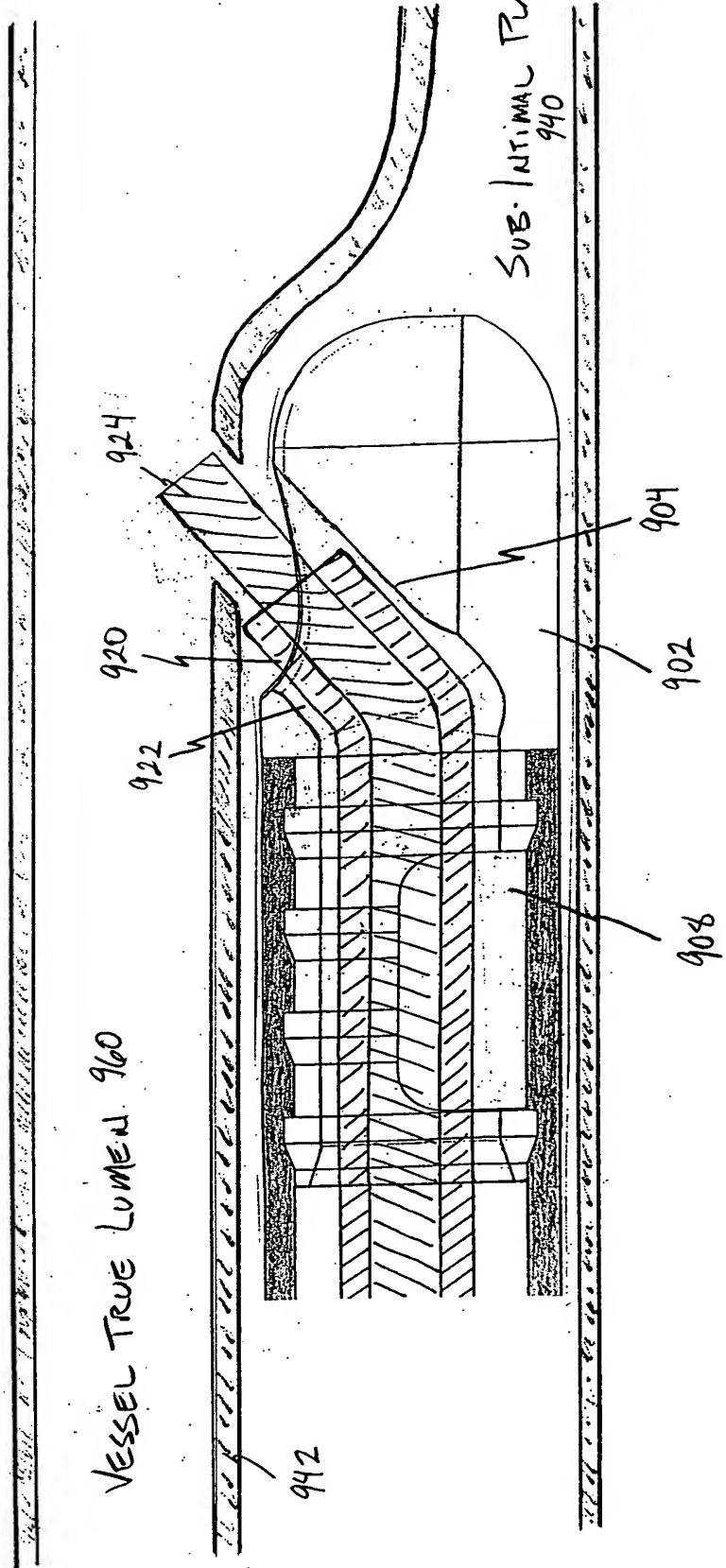


FIGURE 9C

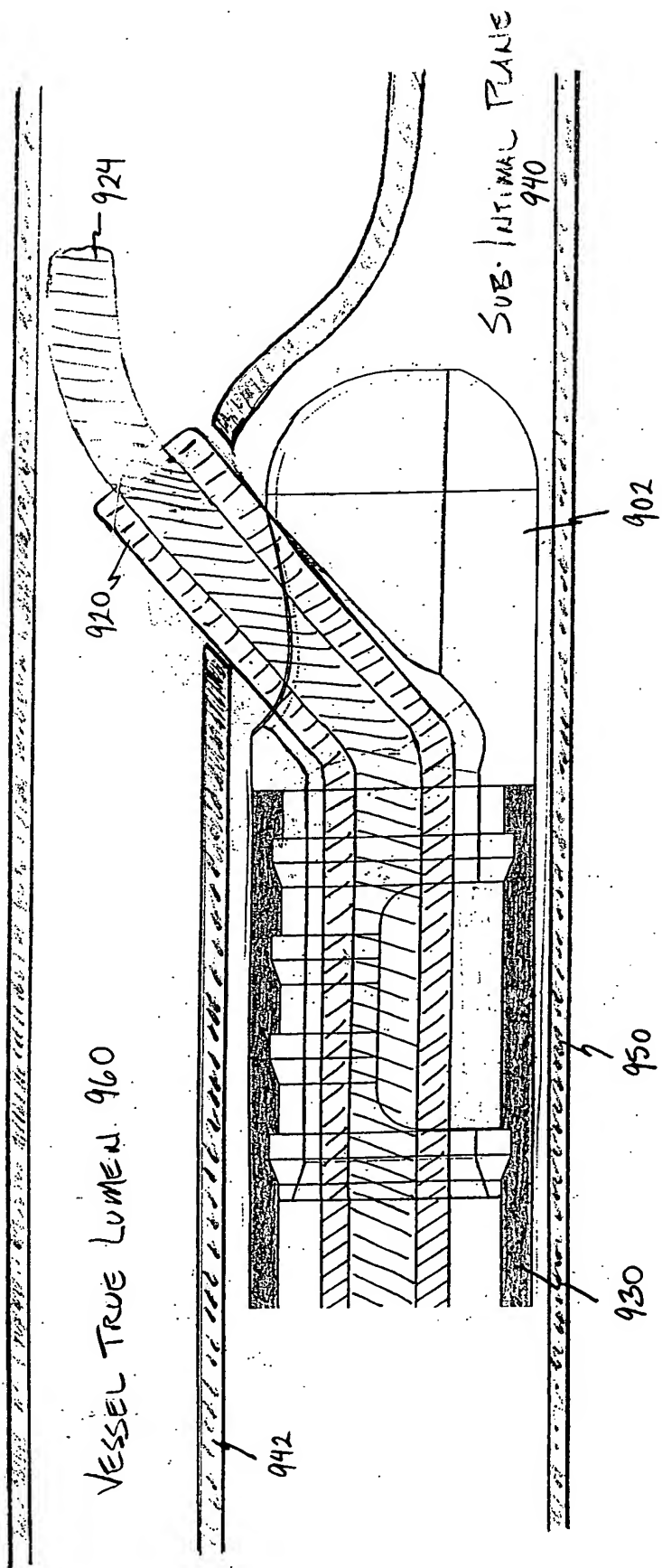


FIGURE 9D

VESSEL TRUE LUMEN 960

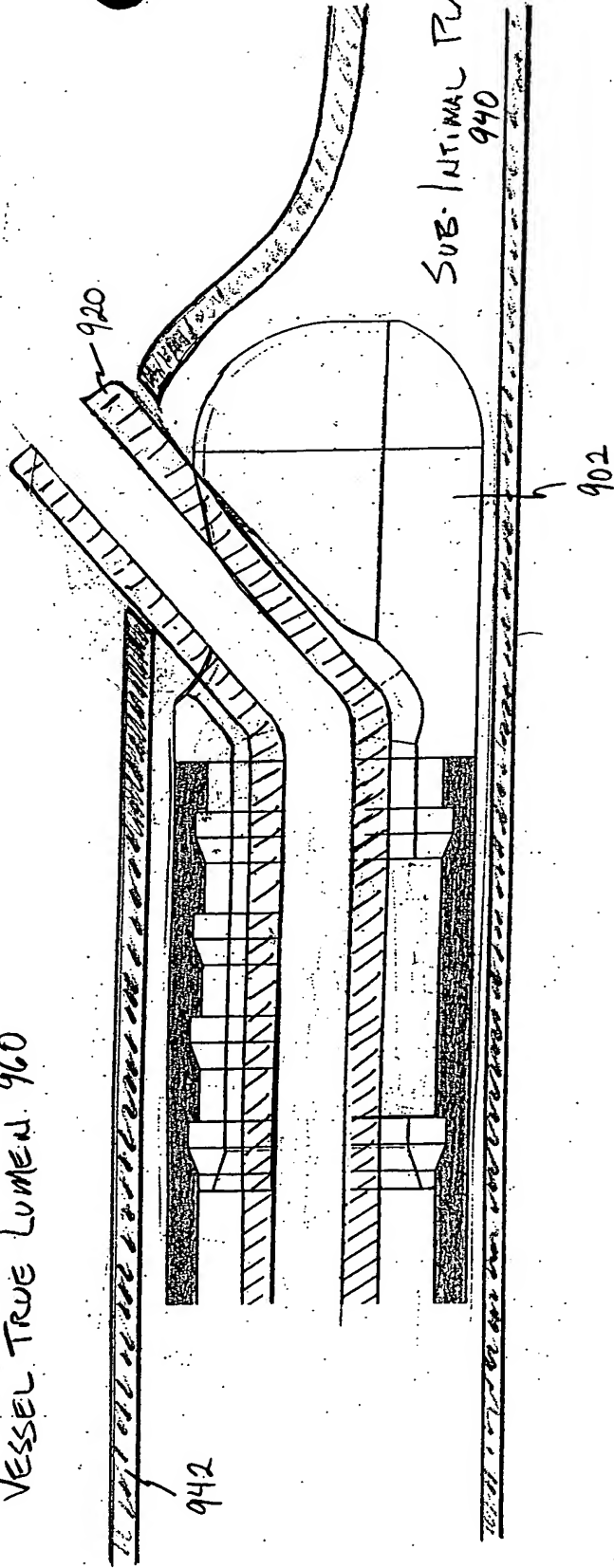


FIGURE 9E

FIG. 9F

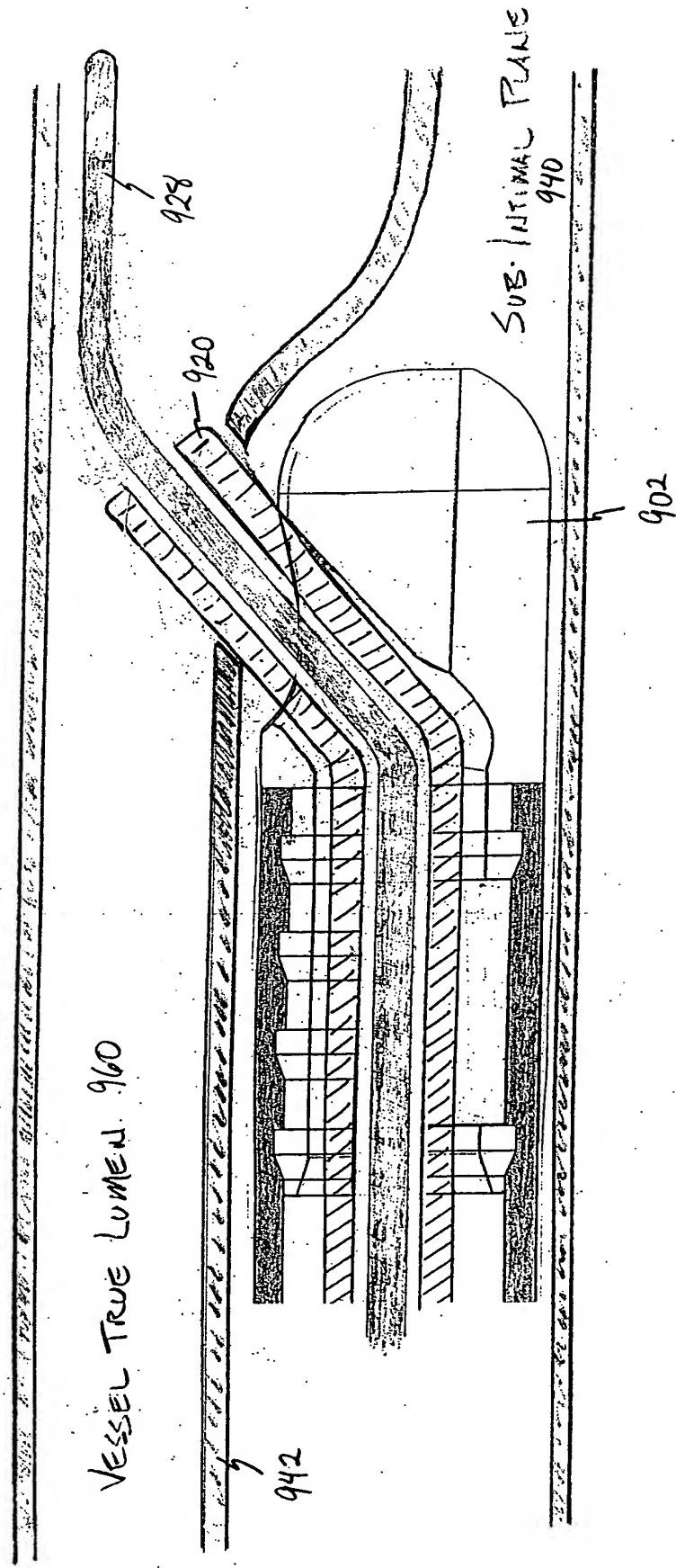


FIGURE 9F

FIG. 10A

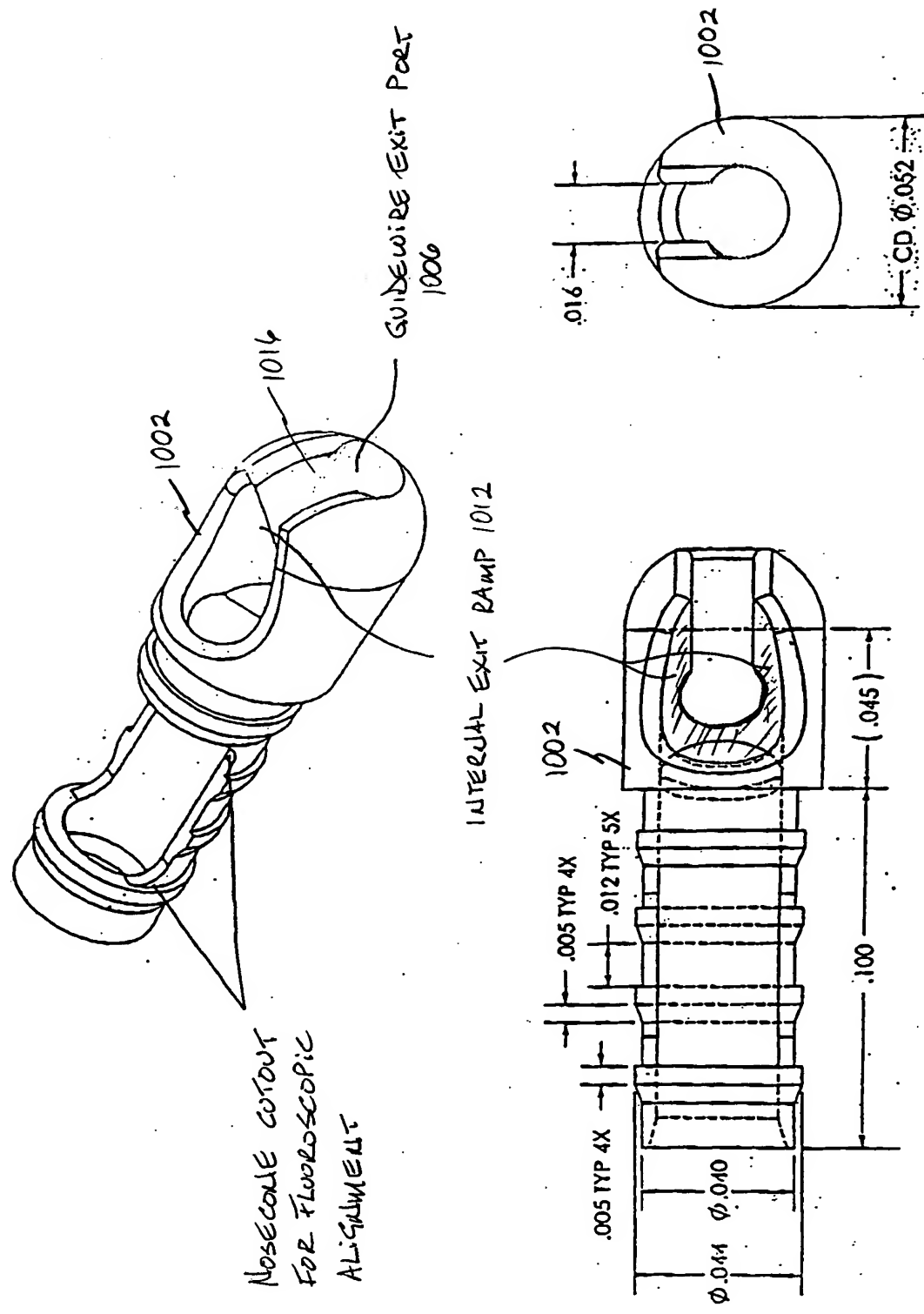


FIGURE 10A

FIG. 10A

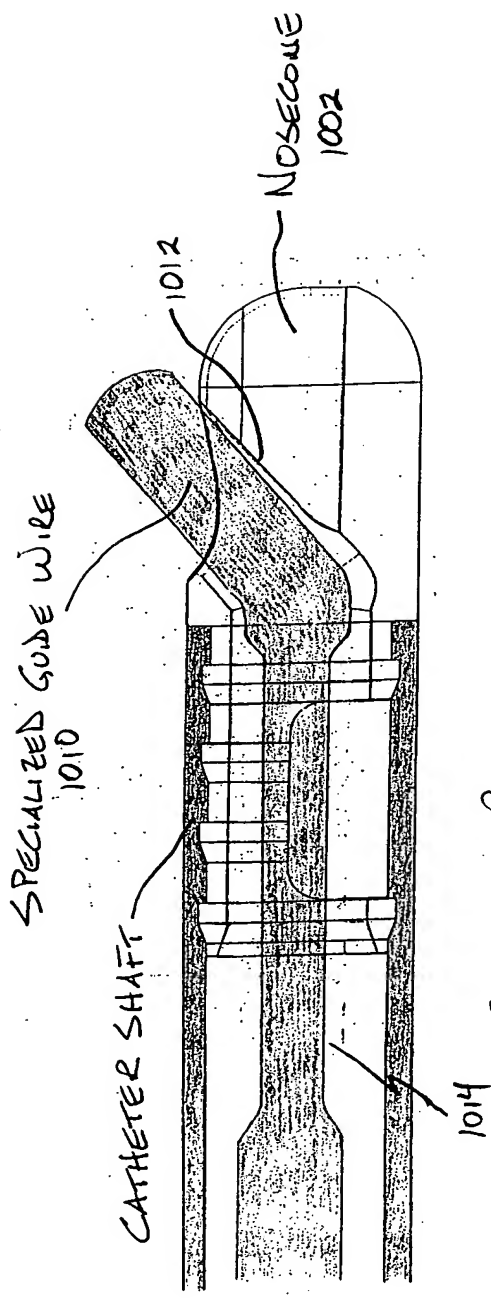


FIGURE 10B

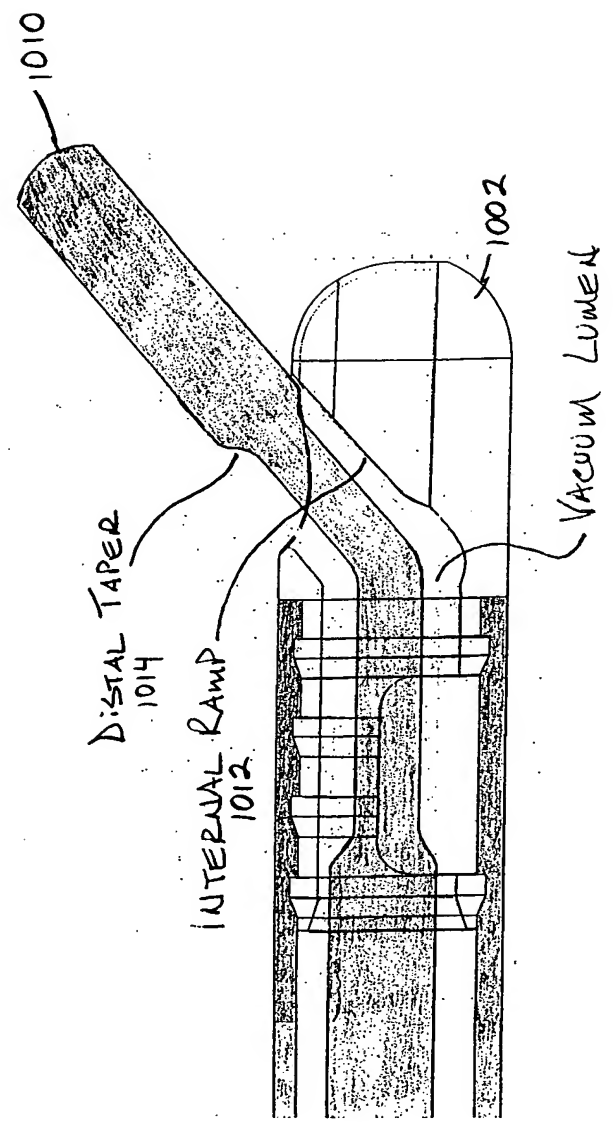
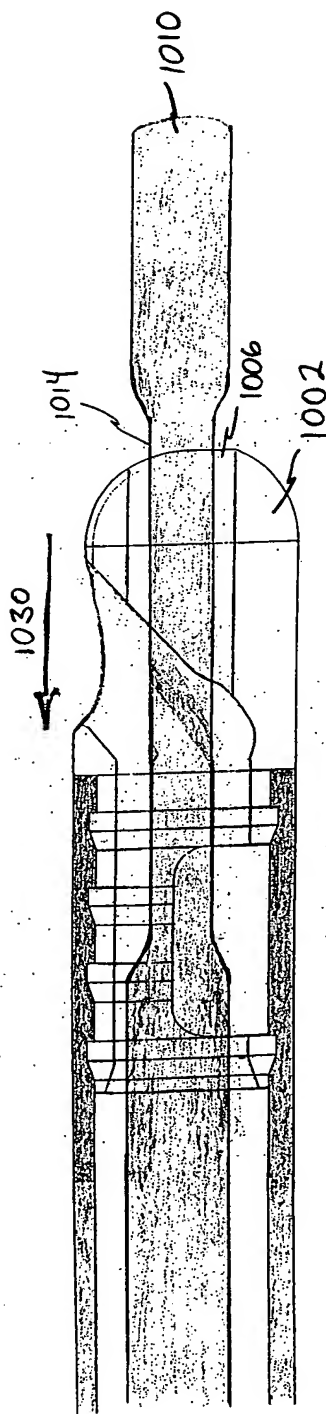
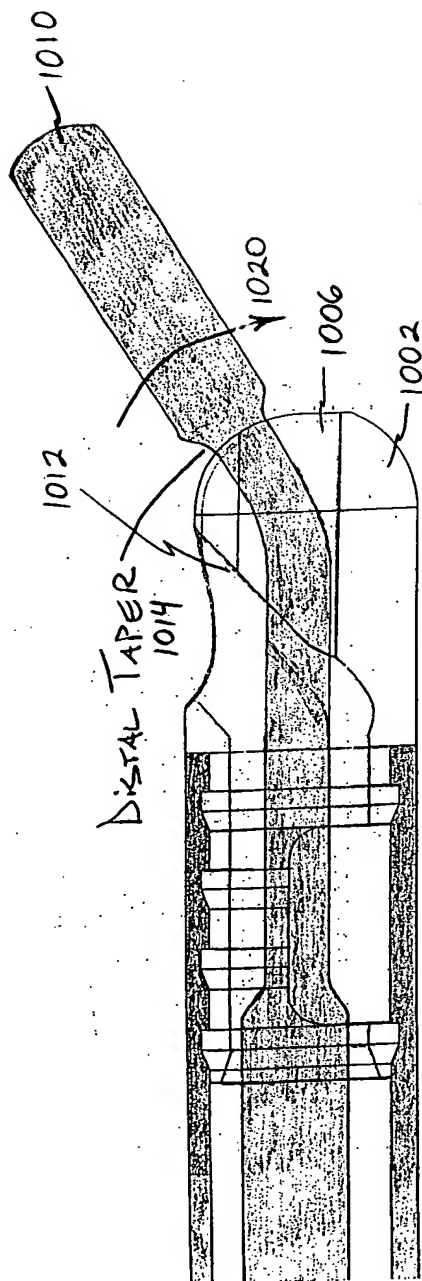


FIGURE 10C



1100
↓

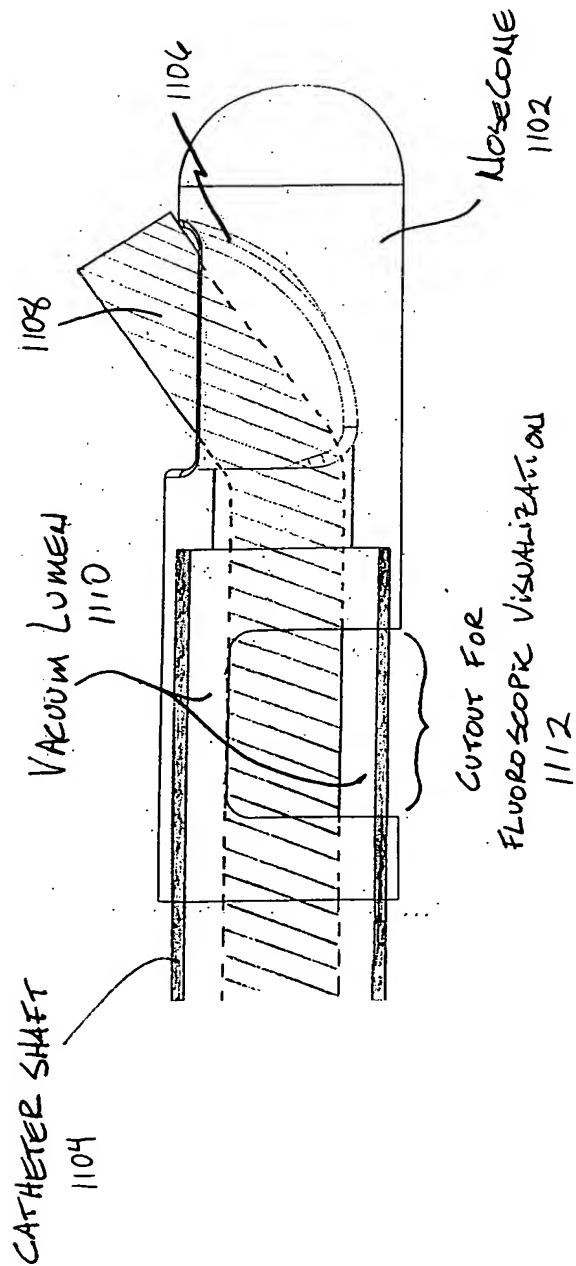


FIGURE 11

FIG. 12A

1200

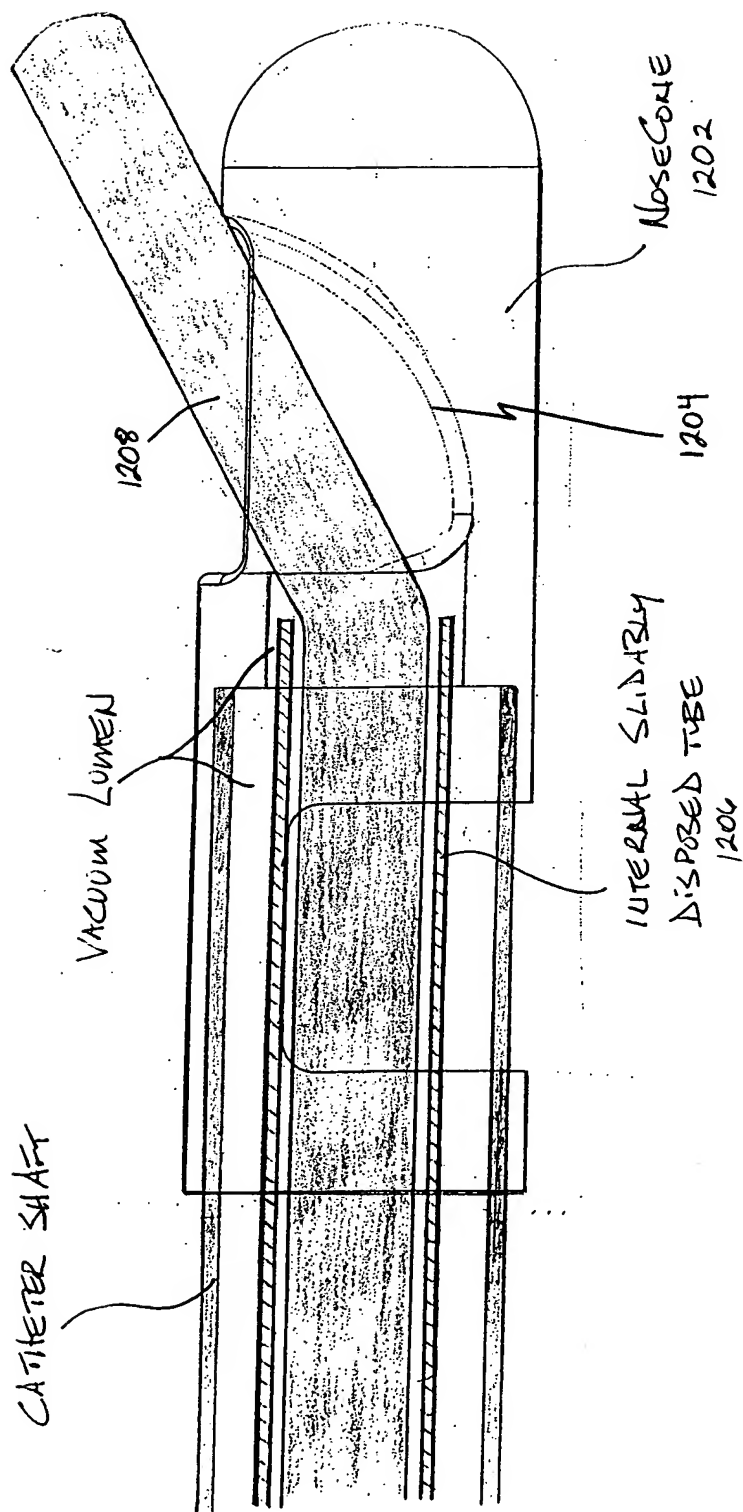


FIGURE 12A

FIG. 12B is a cross-sectional view of the catheter 1200 taken along line 12-12 of FIG. 12A, showing the internal components including the vacuum lumen 1208, the internal slidably disposed tube 1206, and the nosecone 1202.

1200
↓

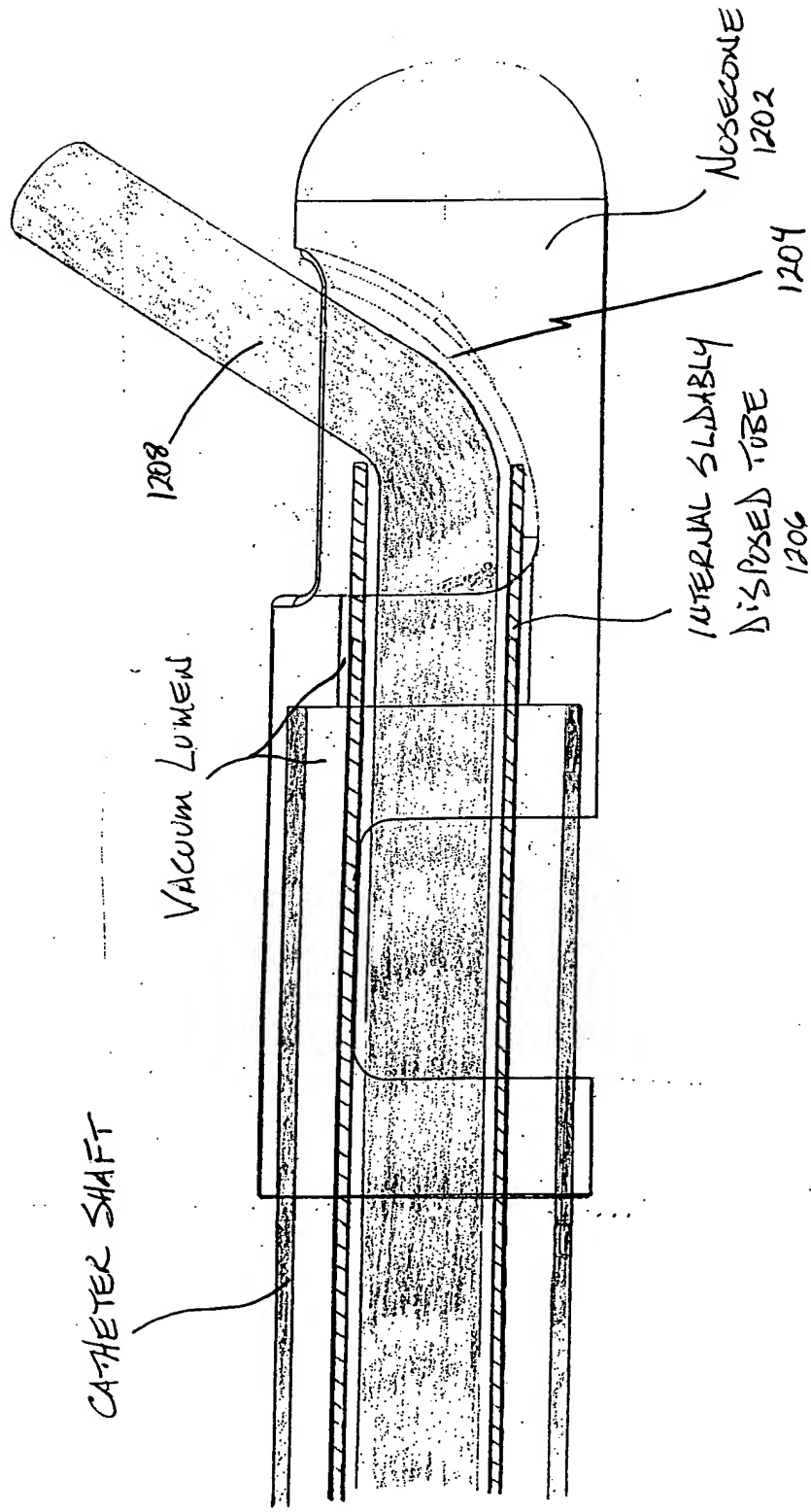


FIGURE 12B

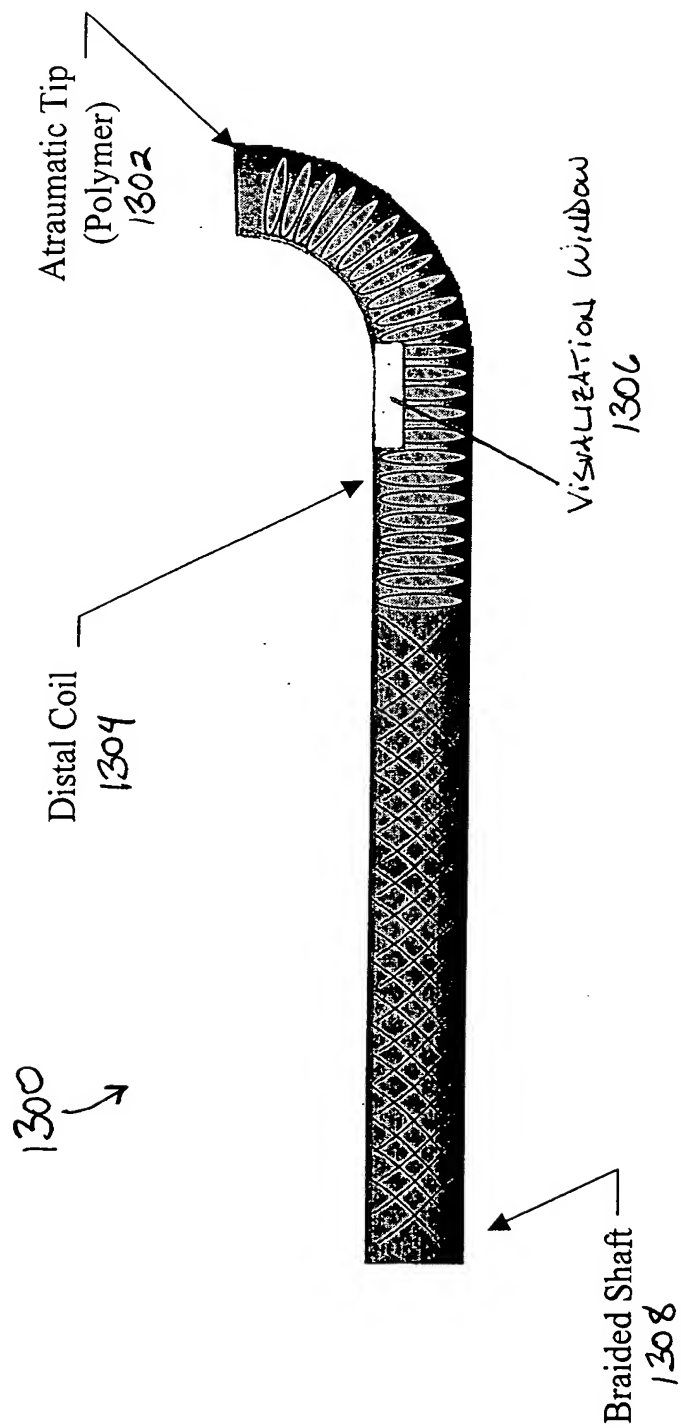


FIGURE 13

1400
↓

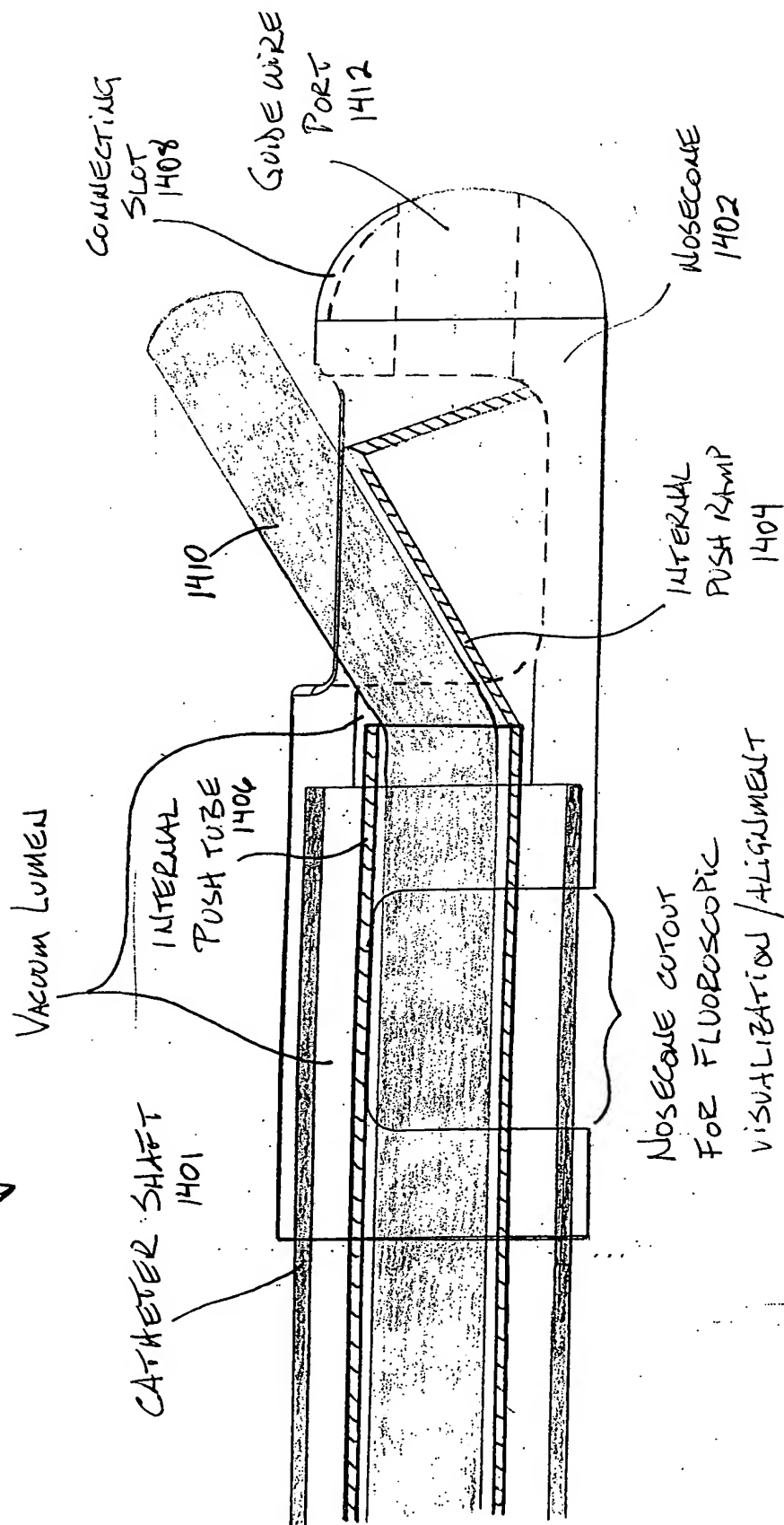


FIGURE 14A

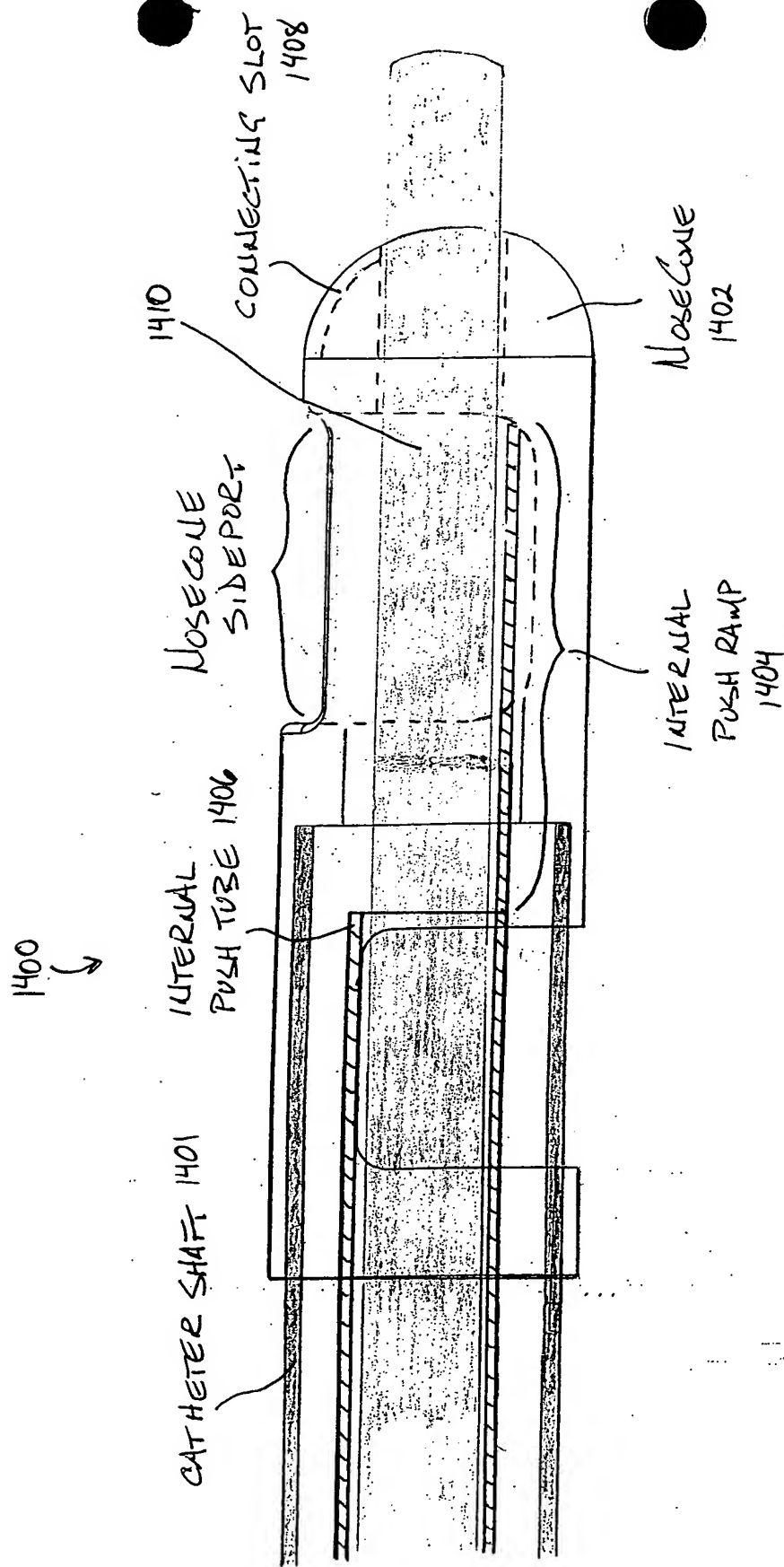


FIGURE 14B

1500

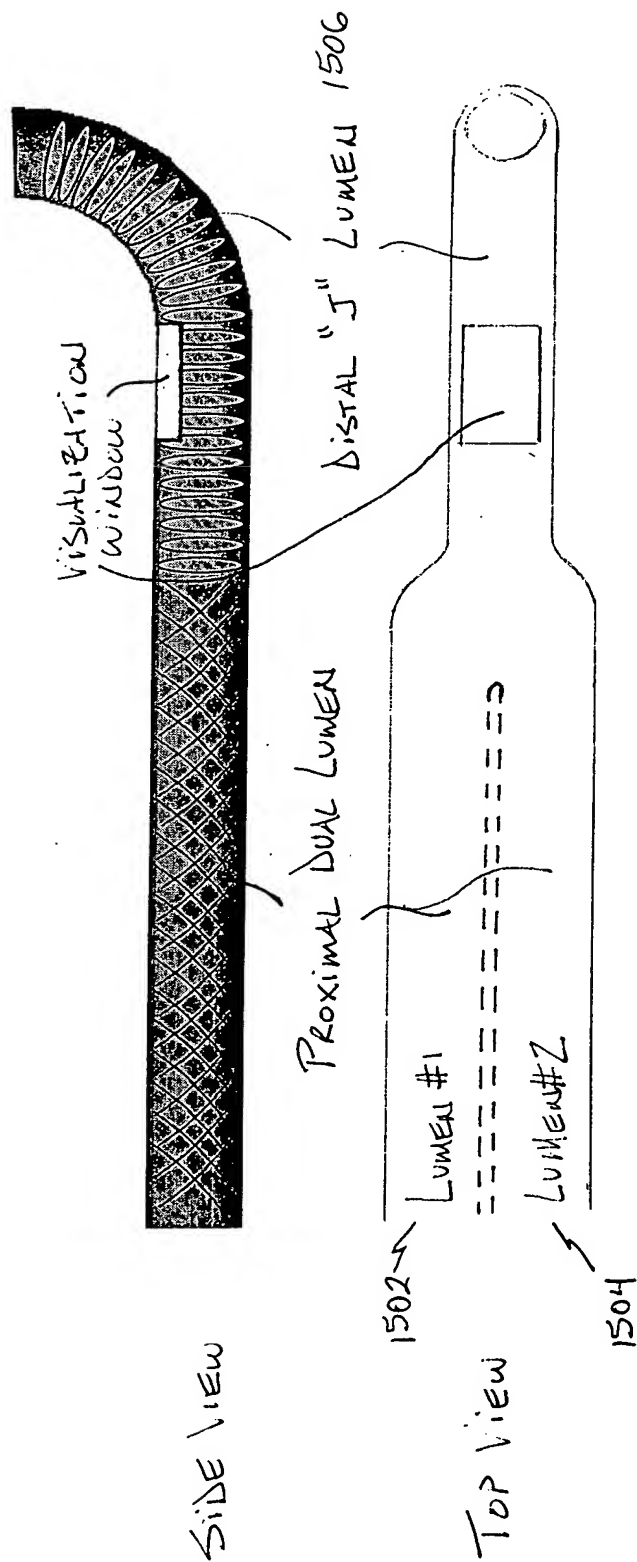


FIGURE 15

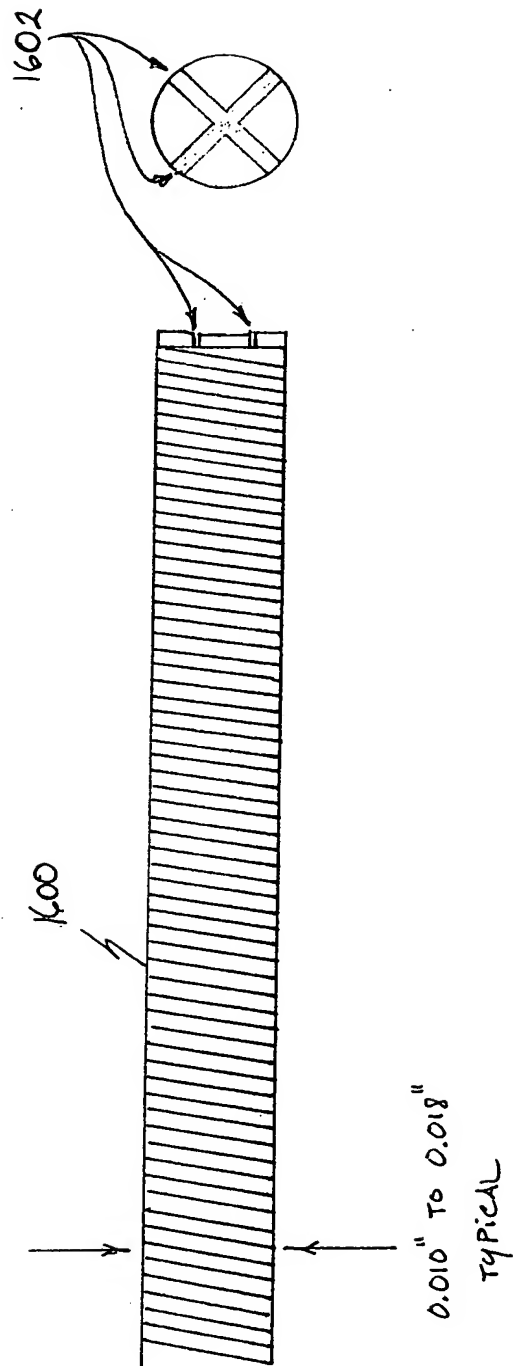


FIGURE 16

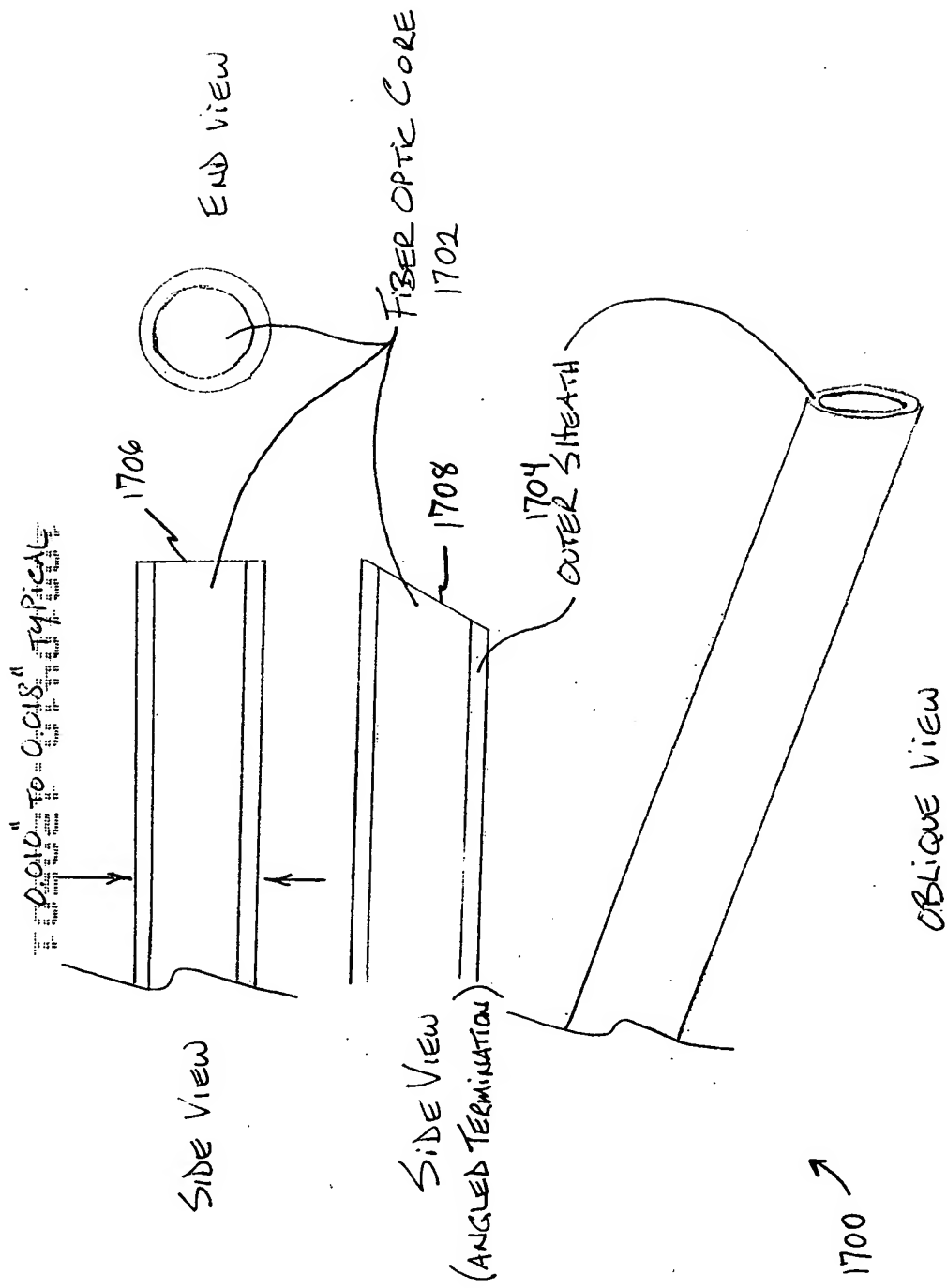


FIGURE 17A

1750

↓

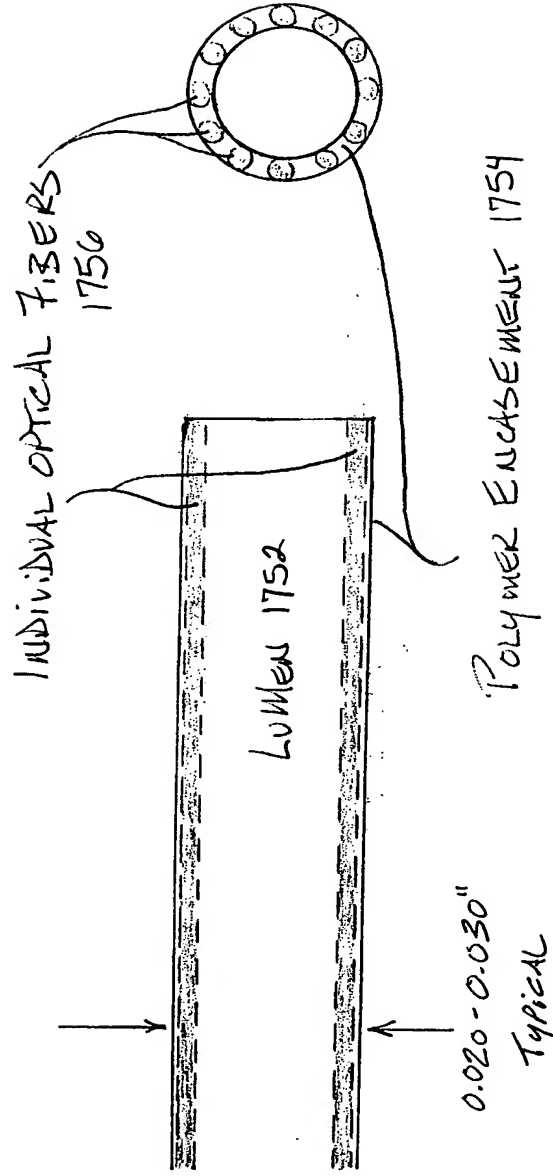


FIGURE 17B

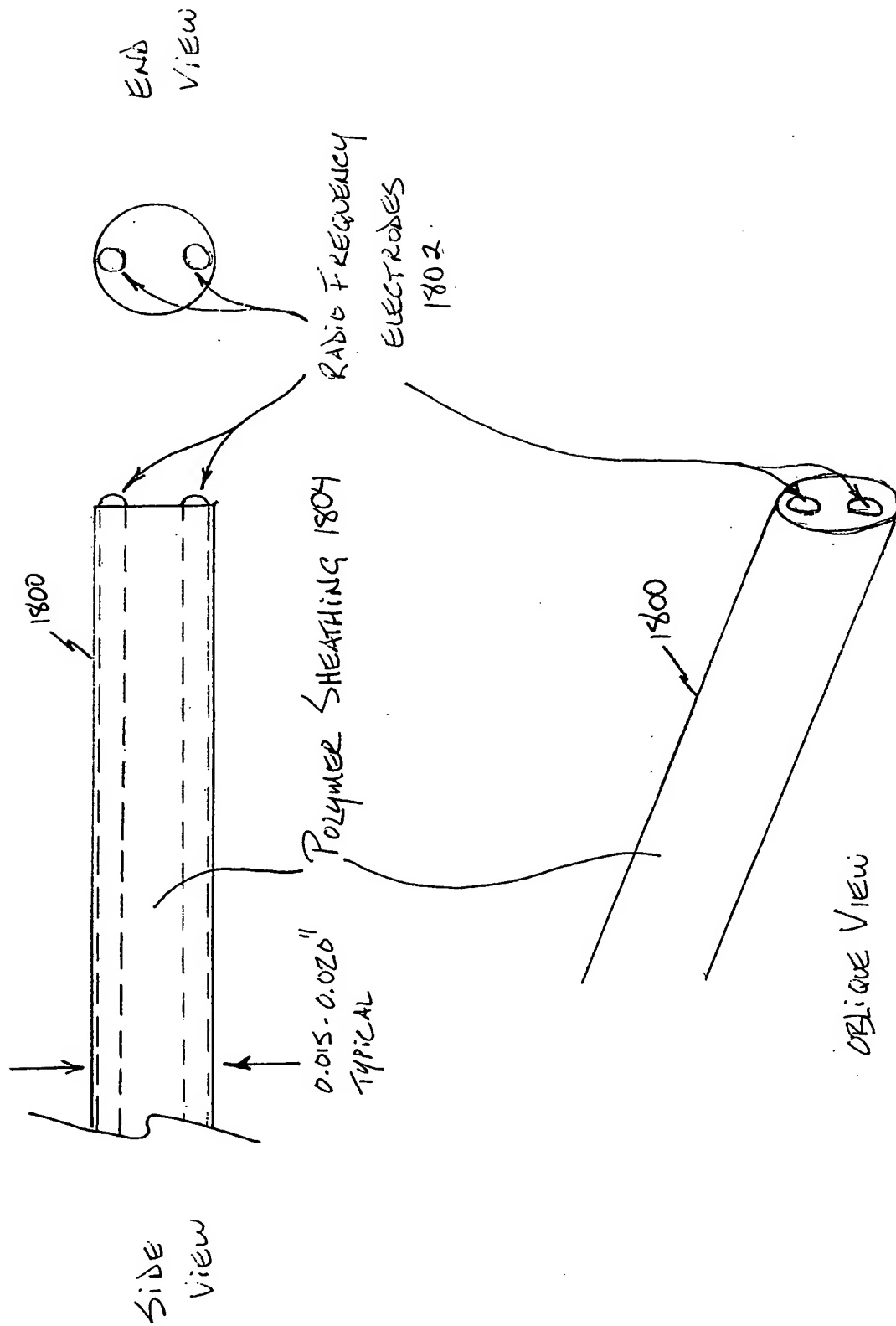


FIGURE 18

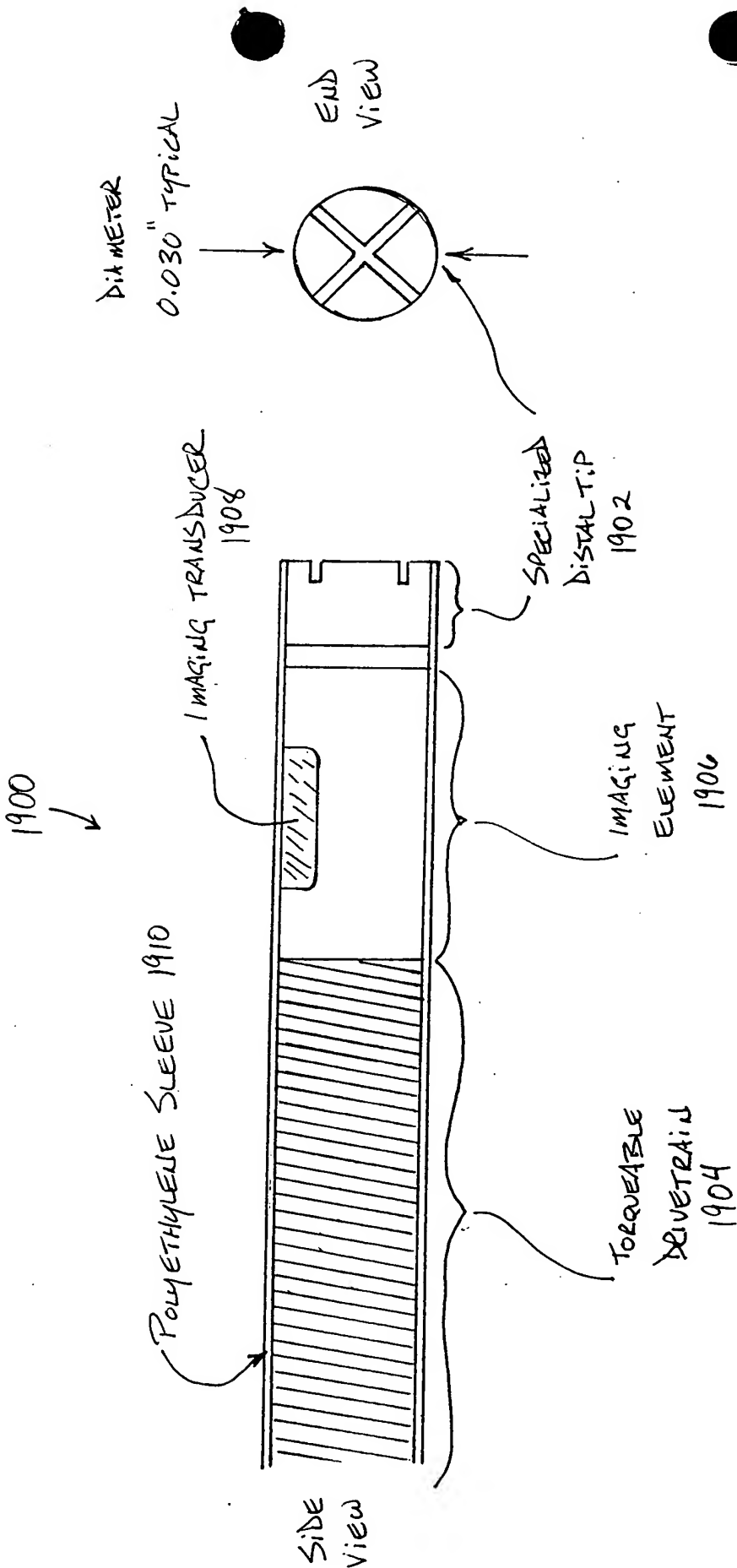


FIGURE 19

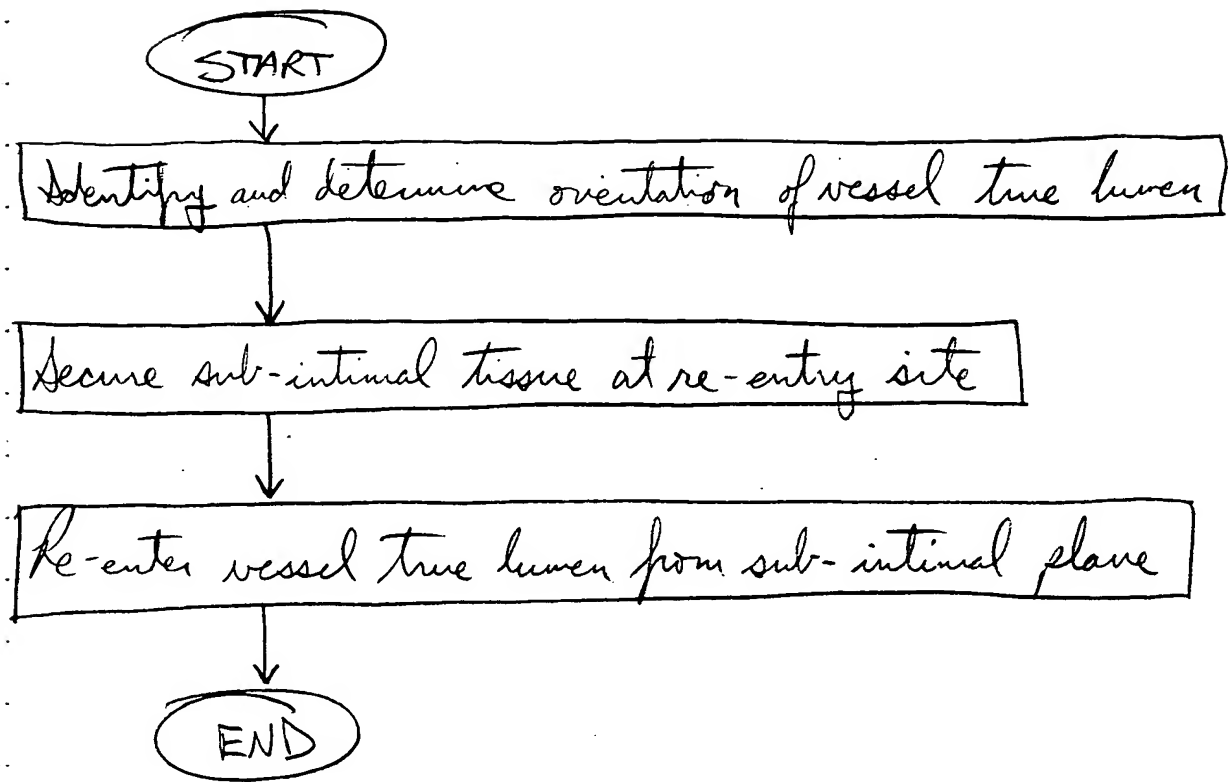


FIGURE 20

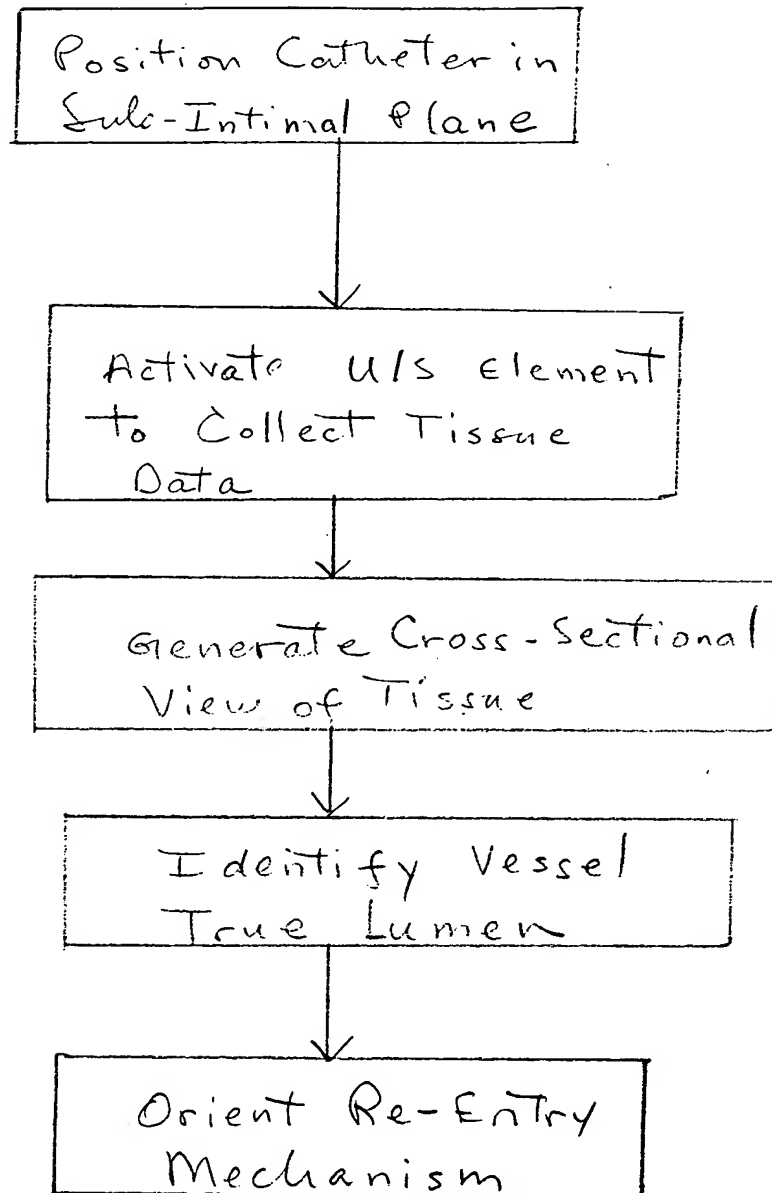


Figure 21

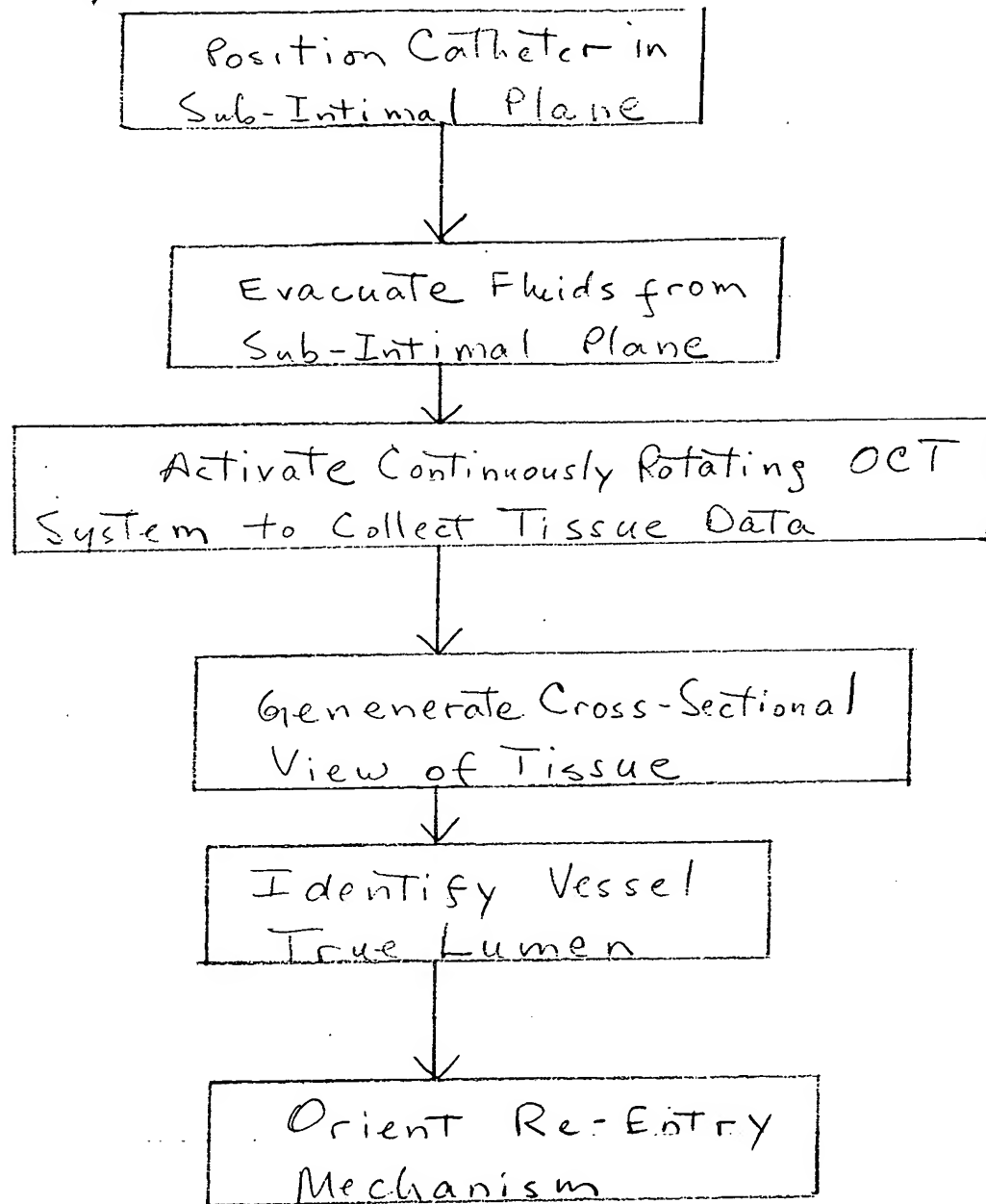


Figure 22

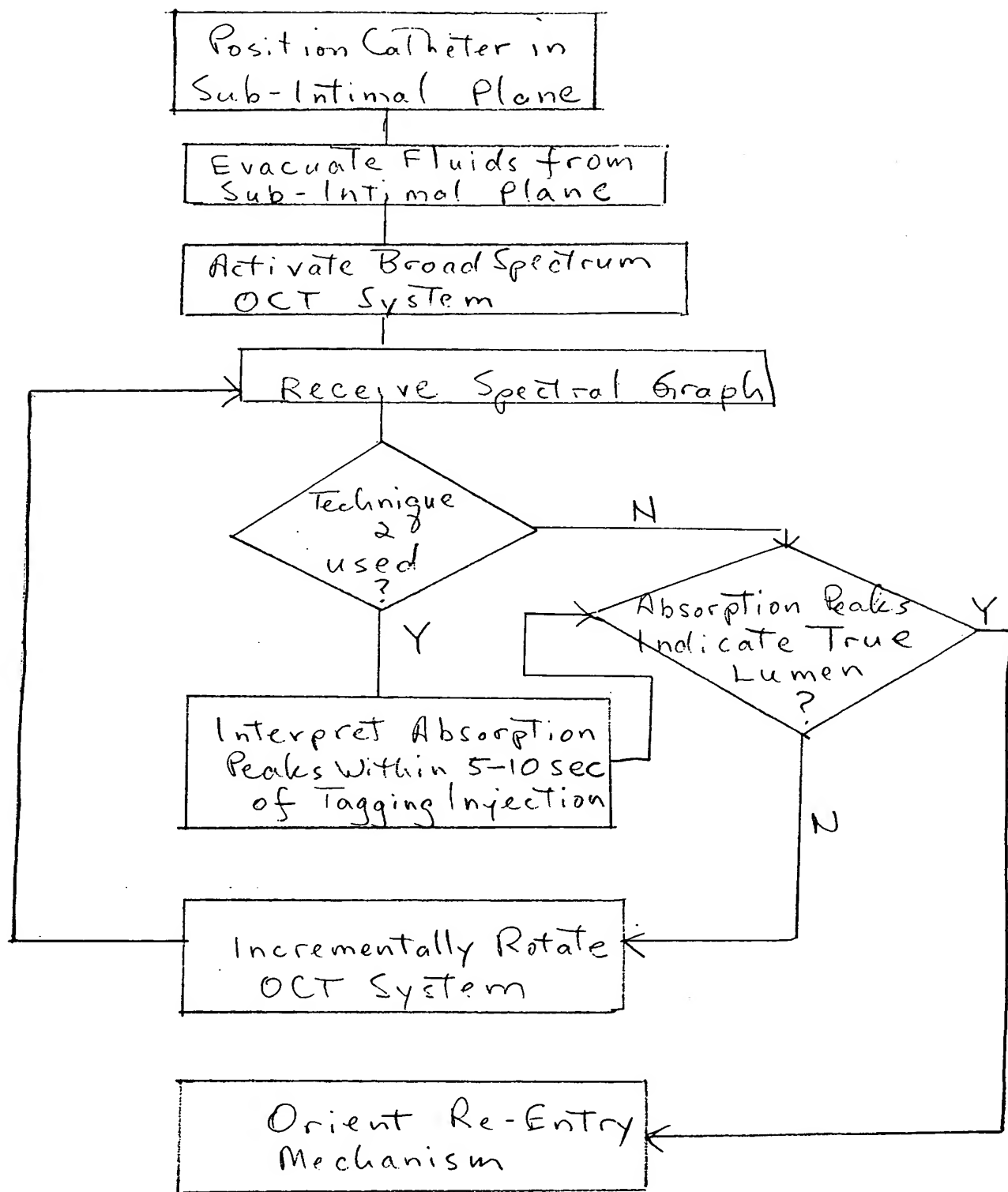


FIGURE 23

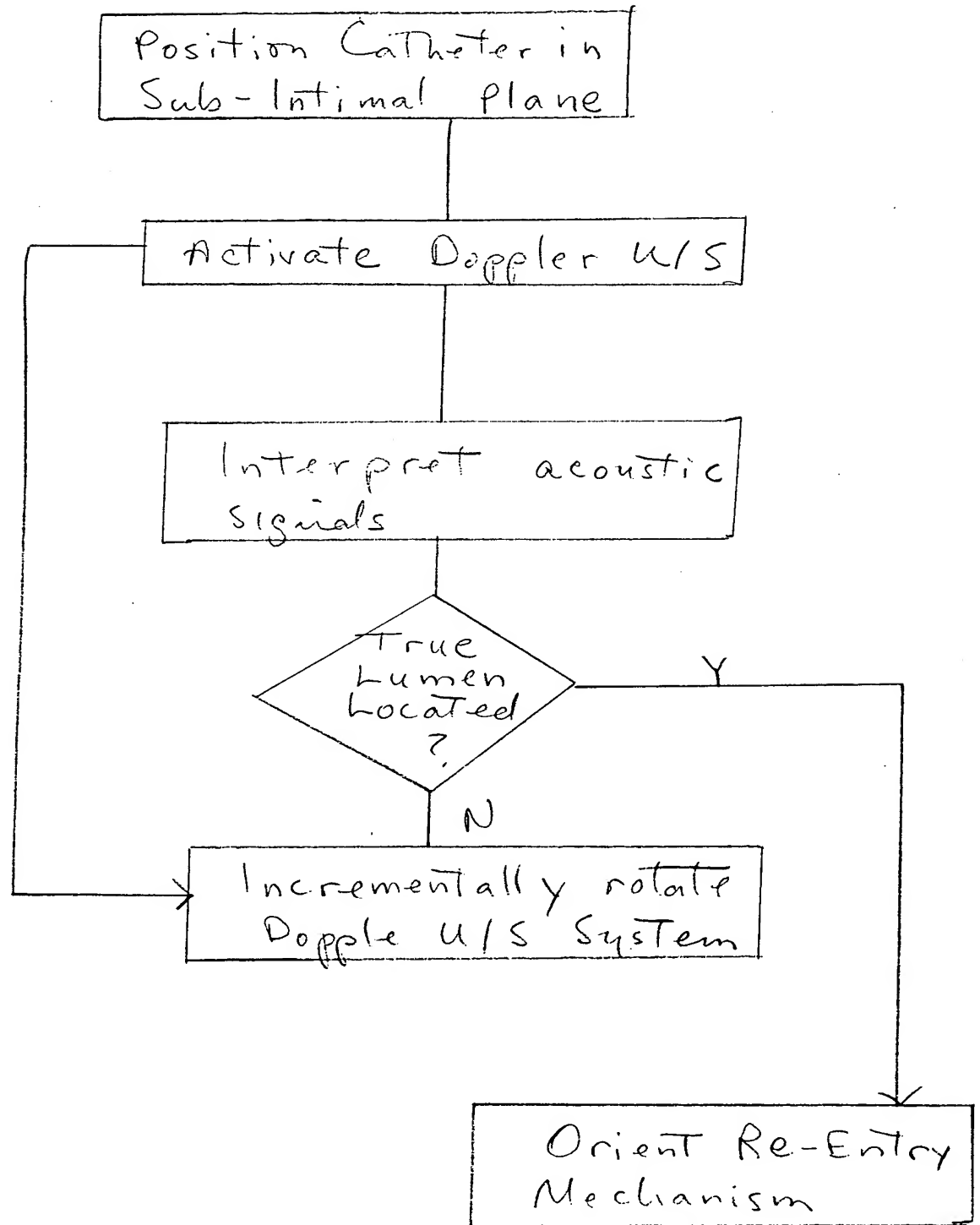


Figure 24

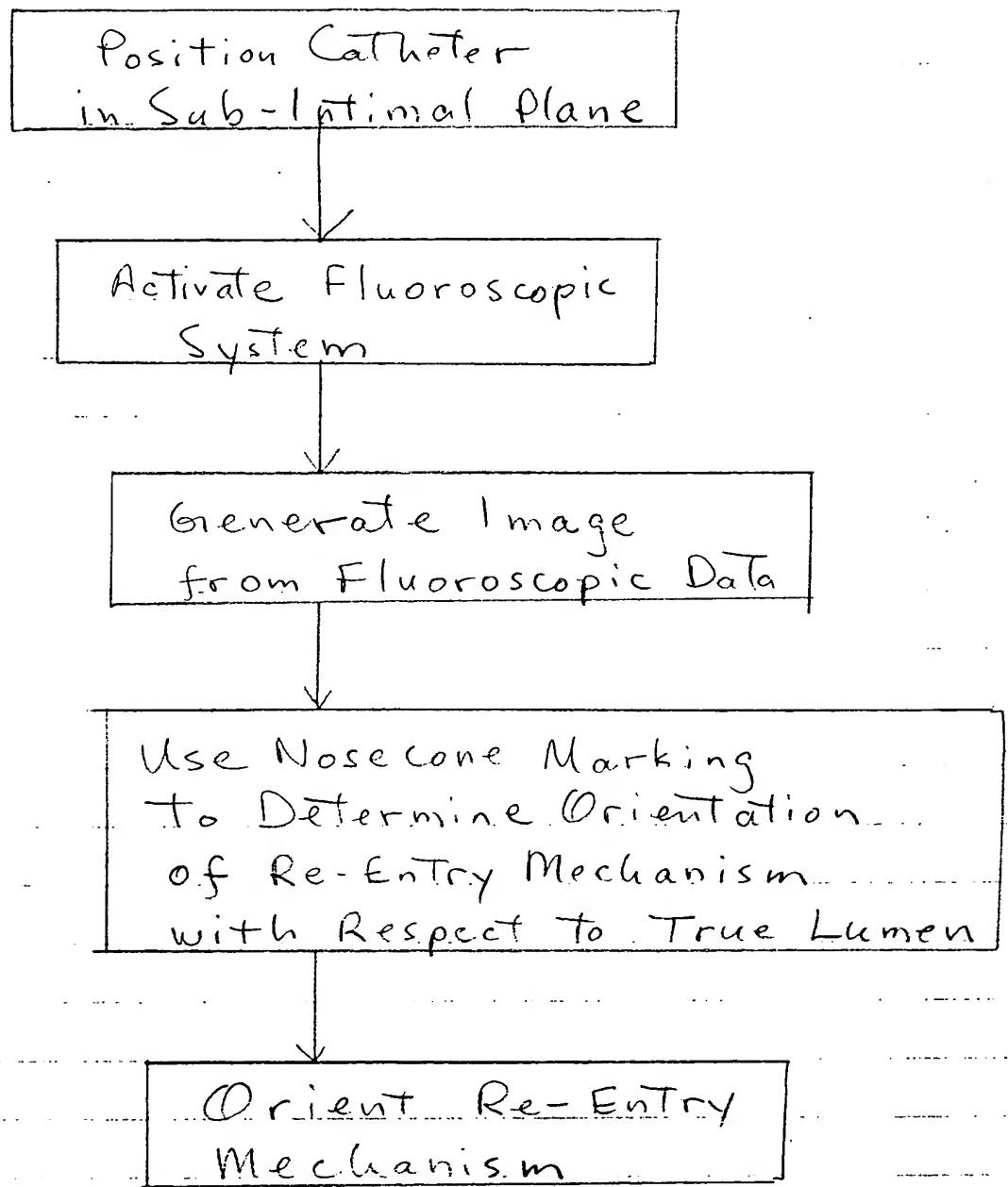


Figure 25.

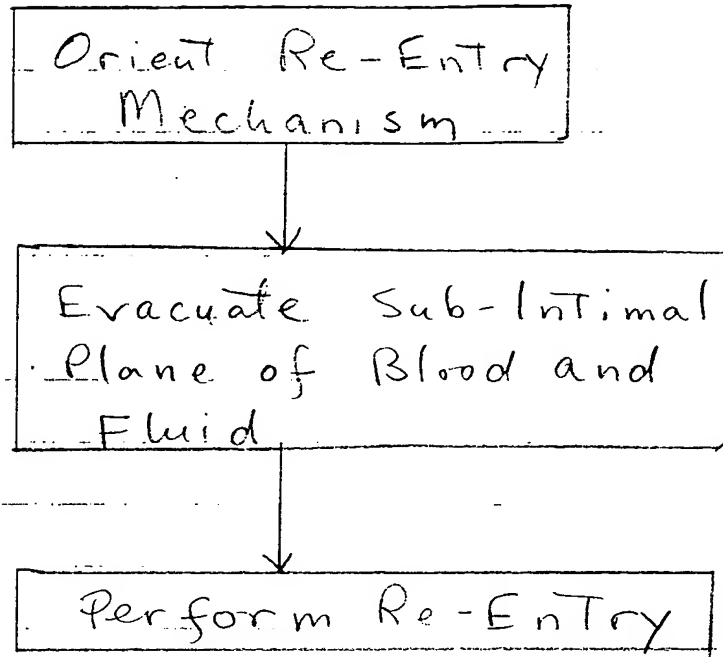


Figure 26

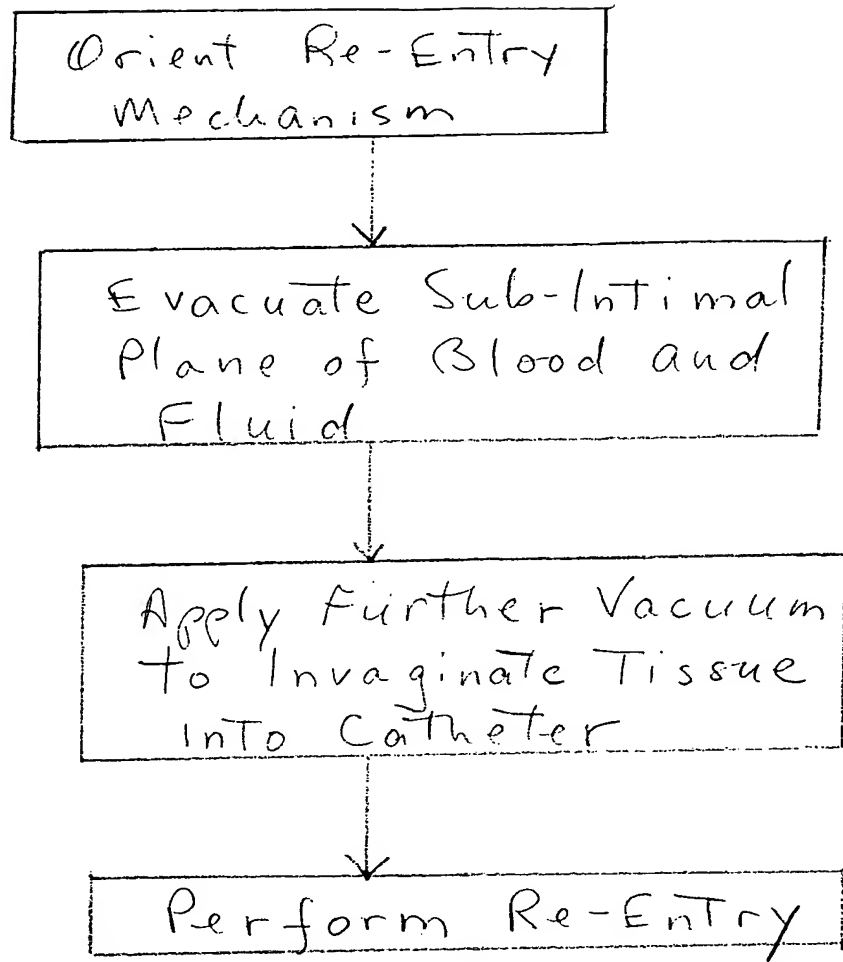


Figure 27

Orient Re-Entry
Mechanism



Evacuate Sub-Intimal
Plane of Blood and
Fluid



Mechanically Secure
Sub-Intimal Tissue
Against or Inside
Nose cone



Perform Re-Entry

Figure 28

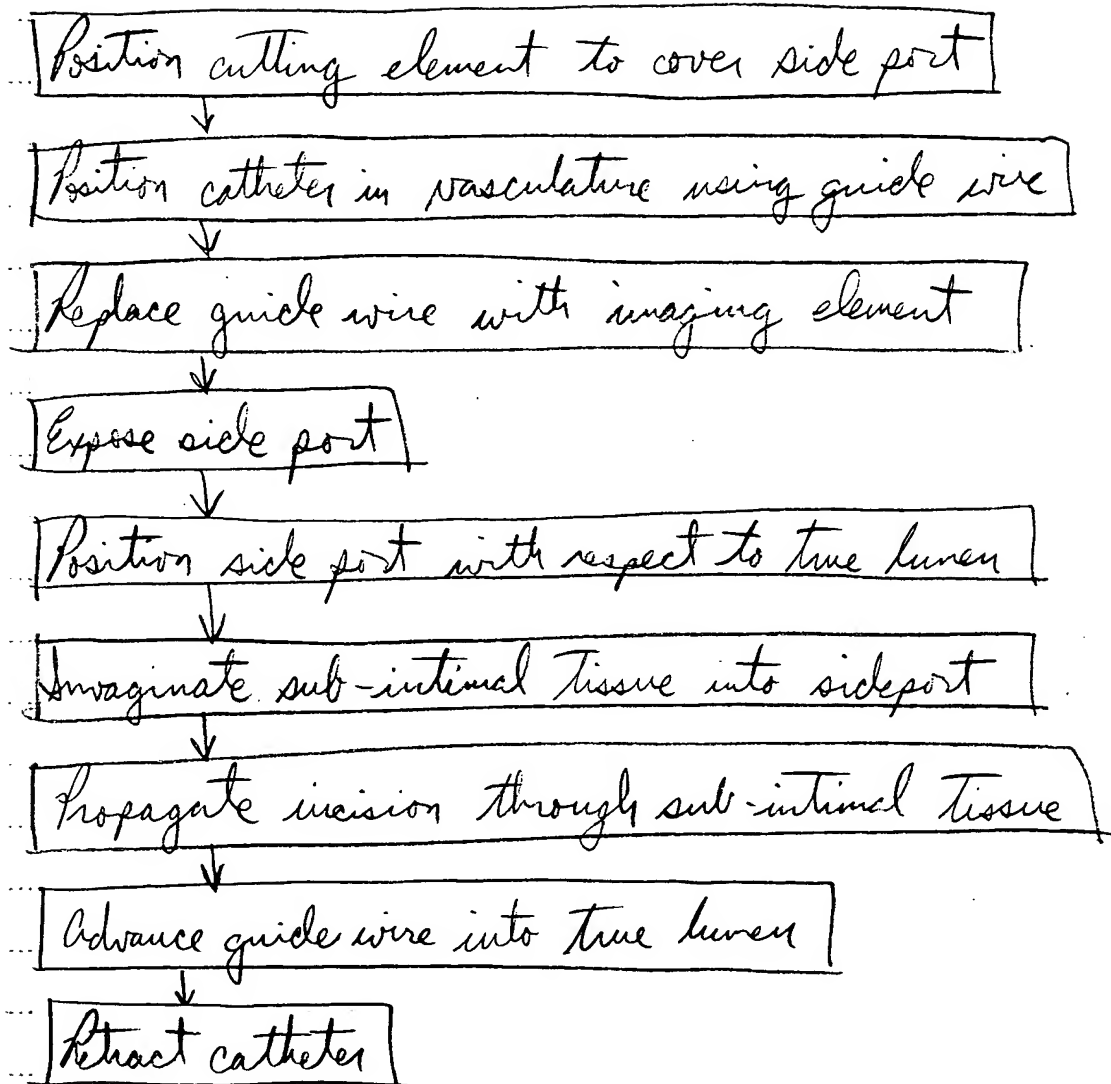


FIGURE 29

Position guide wire in sub-intimal space

↓
Retract cannula

↓
Position catheter in vasculature

↓
Position side port with respect to true lumen

↓
Position guide wire proximal to nosecone distal end

↓
Lock sub-intimal tissue onto nosecone surface using vacuum

↓
Advance cannula distally and guide out of side port via nosecone internal ramps

↓
Pierce sub-intimal tissue

↓
Advance guide wire into true lumen

↓
Retract cannula

FIGURE 30

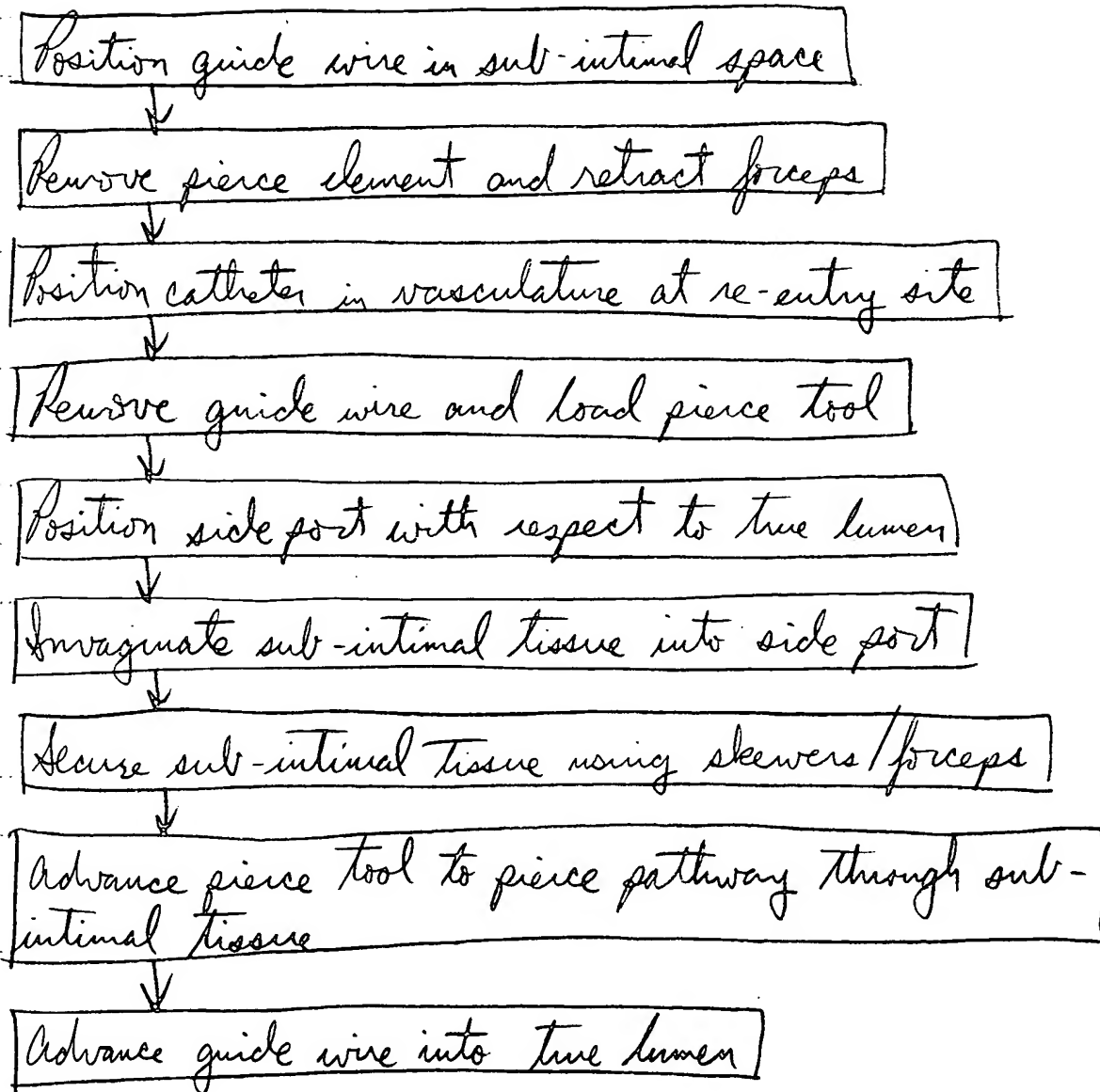


FIGURE 31

Position catheter in vasculature using guide wire



Remove guide wire and advance visualization element



Align side port with respect to vessel true lumen



Lock sub-intimal tissue on surface of catheter using applied vacuum



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 32

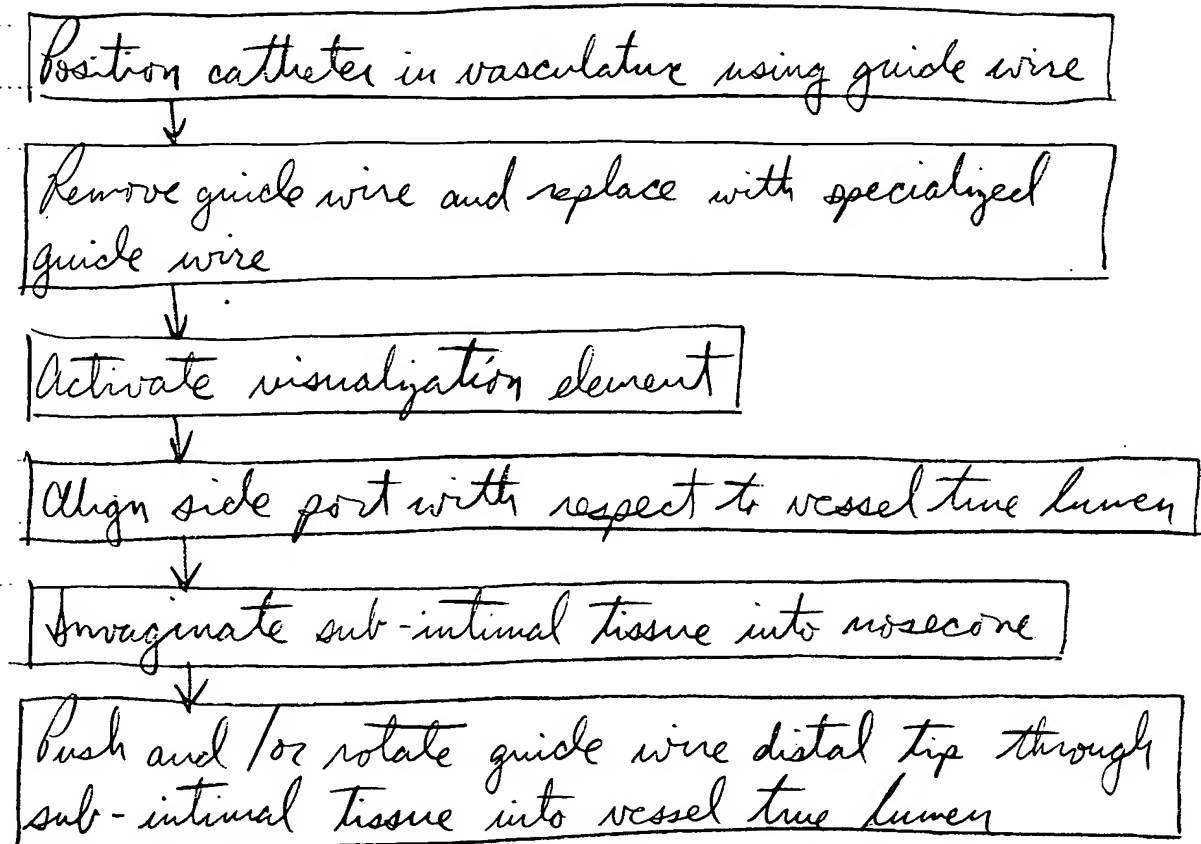


FIGURE 33

Retract cannula

↓
Position catheter in vasculature using guide wire

↓
Align side port with respect to true lumen

↓
Position guide wire proximal to nosecone distal end

↓
Lock sub-intimal tissue onto nosecone using vacuum

↓
Advance cannula distally along internal ramp until in secure purchase with sub-intimal tissue

↓
Advance guide wire until tip coincident with cannula distal tip

↓
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 34

Position catheter in vasculature with respect to vessel true lumen



Advance specialized guide wire proximally relative to distal end of nose cone



Lock sub-intimal tissue onto nosecone using vacuum



Rotate/advance specialized guide wire to engage internal rails of nosecone



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen



Advance specialized guide wire further distally until tapered section translates through nosecone slot into nosecone distal end port



Retract catheter

FIGURE 35

Position catheter in vasculature with respect to vessel true lumen

↓
Retract guide wire and advance visualization element

↓
Rotate side port to face re-entry site

↓
Remove visualization element and advance guide wire

↓
Lock sub-intimal tissue onto nosecone using vacuum

↓
Advance guide wire into nosecone until in contact with sub-intimal tissue

↓
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

↓
Retract catheter

FIGURE 36

Position guide wire appropriately in vasculature

Retract push tube

Advance catheter to vascular region of occlusion over the guide wire

Control guide wire deployment angle from nose cone with position of push tube

Advance push tube distally to position guide wire at re-entry site

Push guide wire through sub-intimal tissue into vessel true lumen

FIGURE 37

Position guide wire appropriately in vasculature



Advance catheter over guide wire to vascular region of occlusion



Retract guide wire distal end into catheter, allowing "J" tip to re-form



Align catheter with respect to re-entry site



Apply vacuum to evacuate sub-intimal plane



Advance guide wire into contact with sub-intimal tissue



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen



Retract catheter

FIGURE 38

Retract push tube



Advance catheter over guide wire to vascular region of occlusion



Retract guide wire to a position proximal to the internal ramp



Align catheter with respect to re-entry site



Evacuate sub-intimal plane using vacuum



Advance push tube to deploy internal push ramps



Advance guide wire into contact with sub-intimal tissue via deployed push ramps



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen



Retract catheter

FIGURE 39

Load a first lumen with working element

Advance catheter over guide wire to vascular region of occlusion using a second lumen

Retract guide wire distal end into catheter, allowing "J" tip to re-form

Align catheter with respect to re-entry site

Evacuate sub-intimal plane

Establish path into vessel true lumen using working element

Retract working element

Advance guide wire into vessel true lumen

Retract catheter

FIGURE 40

Load a first lumen with visualization element

↓
Advance catheter over guide wire to vascular region of occlusion using a second lumen

↓
Remove guide wire and replace with re-entry wire

↓
Advance visualization element into distal single lumen

↓
Align catheter with respect to re-entry site

↓
Retract visualization element to dual lumen region

↓
Evacuate sub-intimal plane

↓
Establish path into vessel true lumen using re-entry wire

↓
Remove re-entry wire and replace with guide wire into vessel true lumen

↓
Retract catheter

FIGURE 41

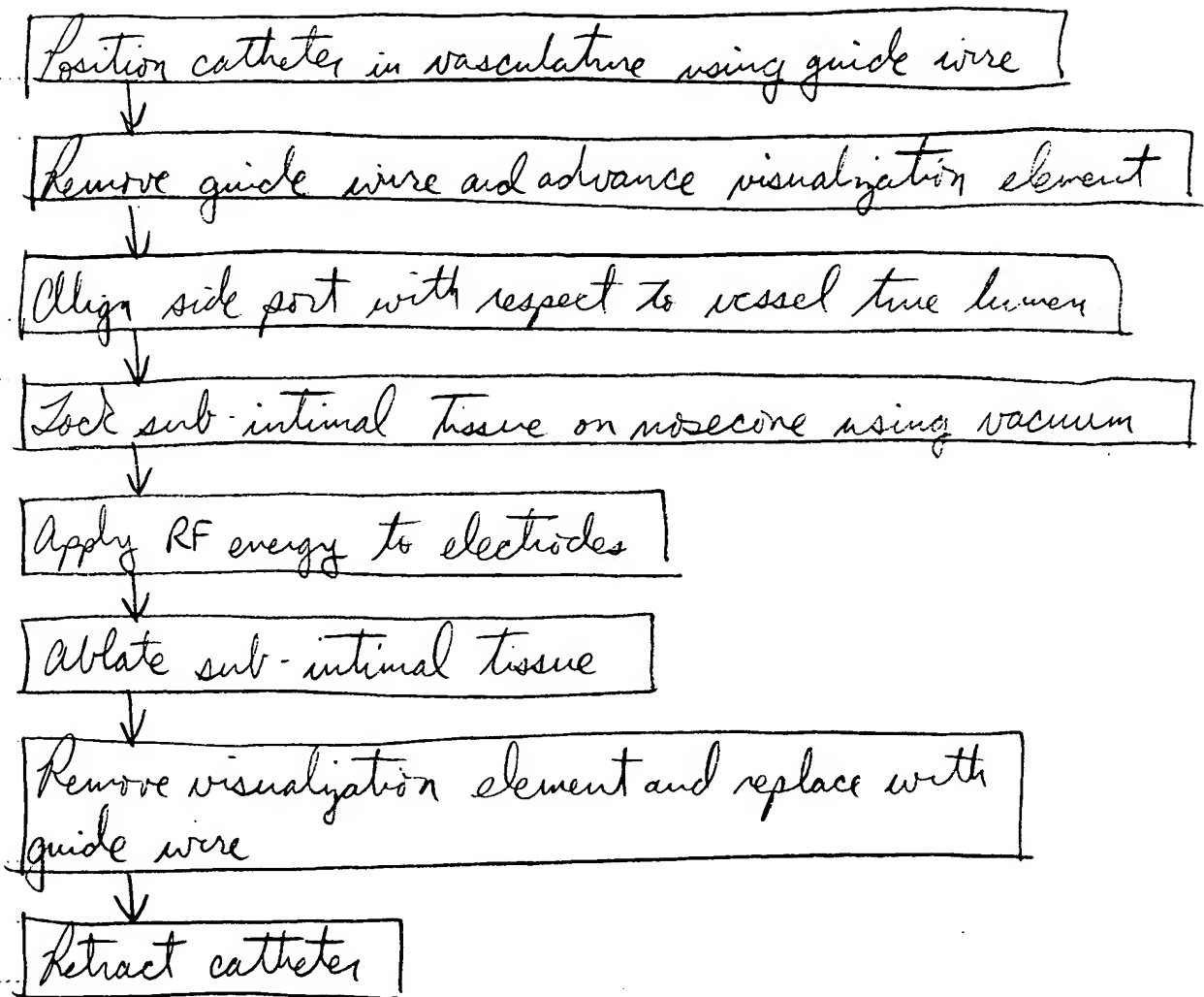


FIGURE 42

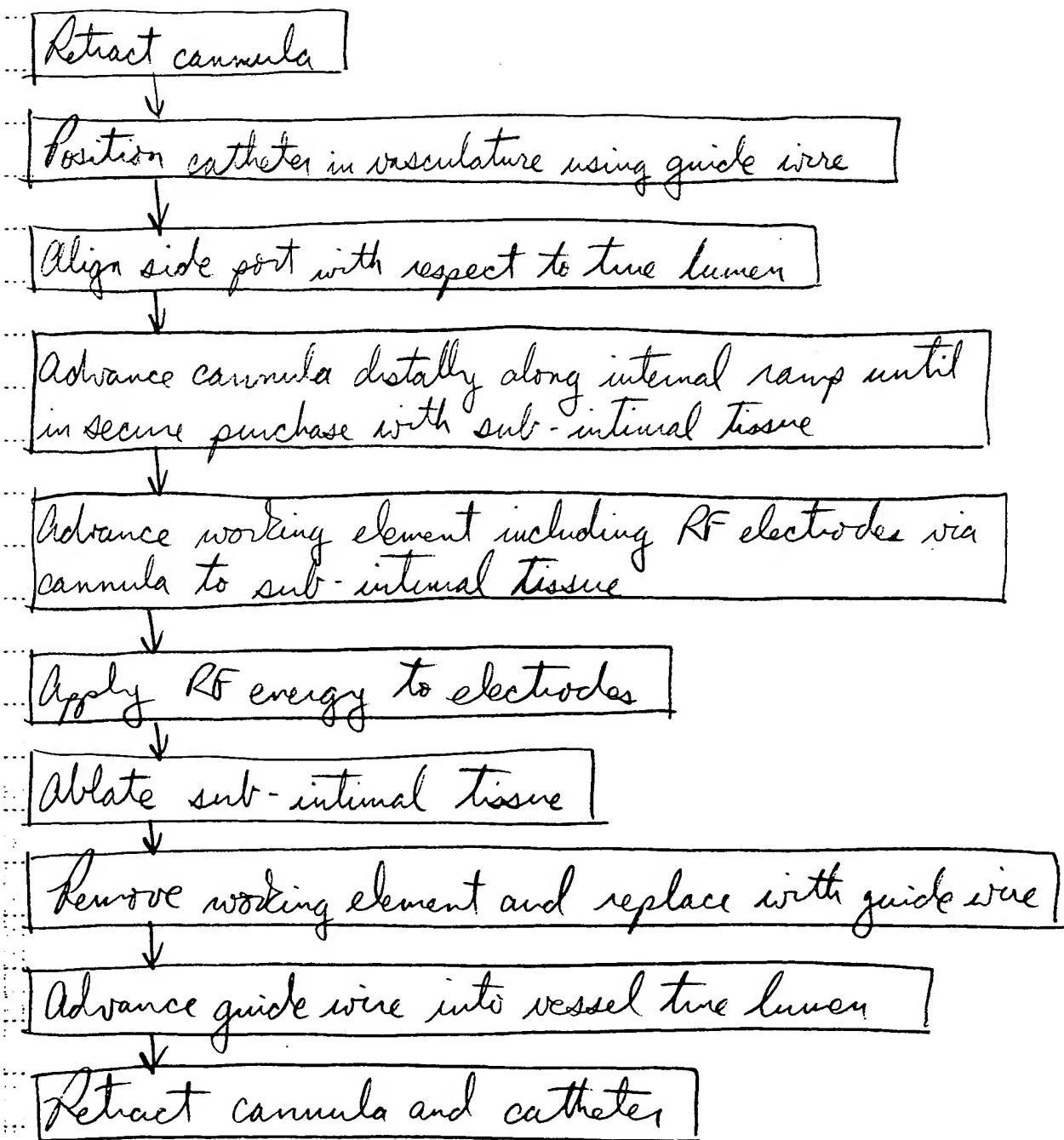


FIGURE 43

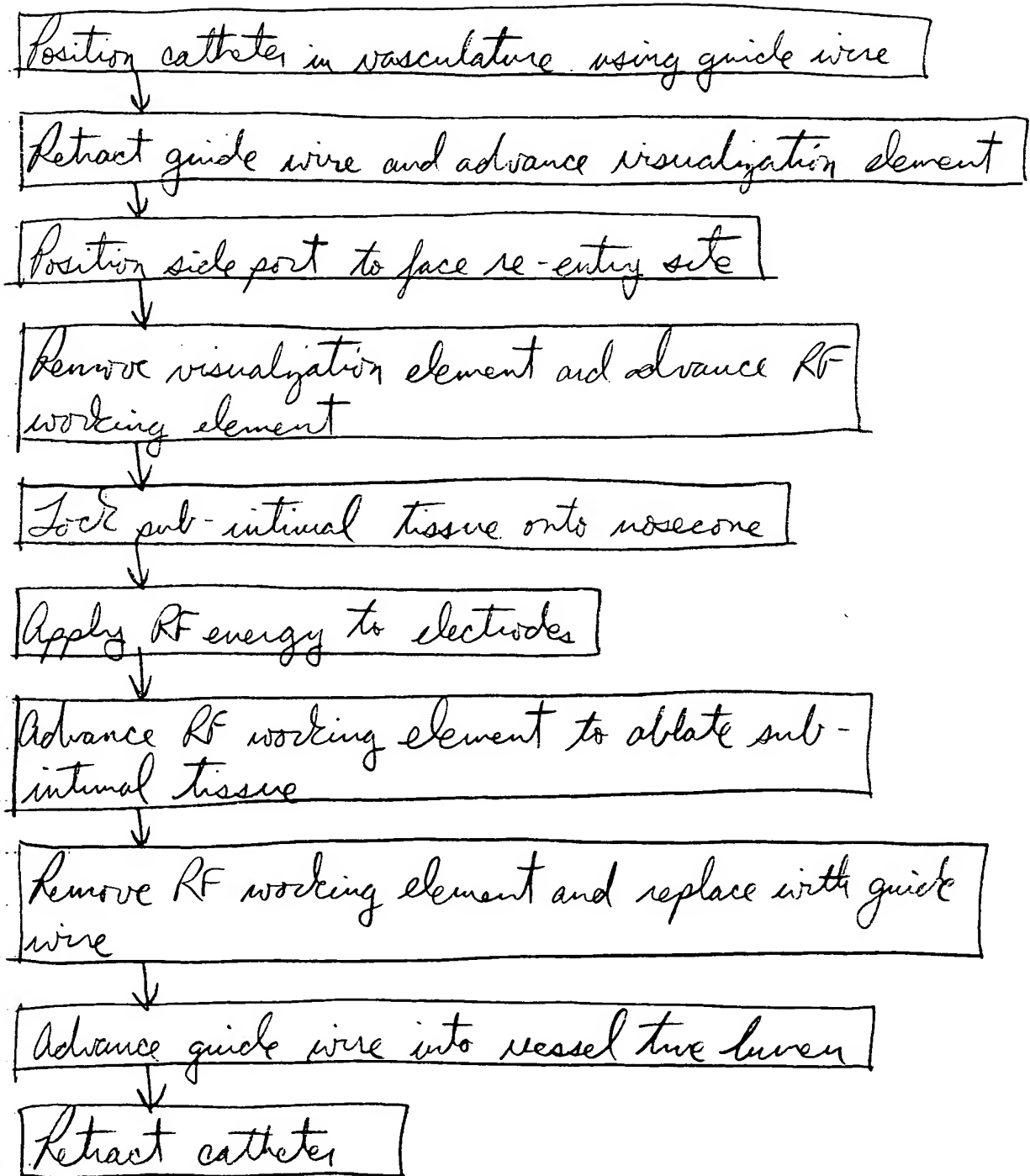


FIGURE 44

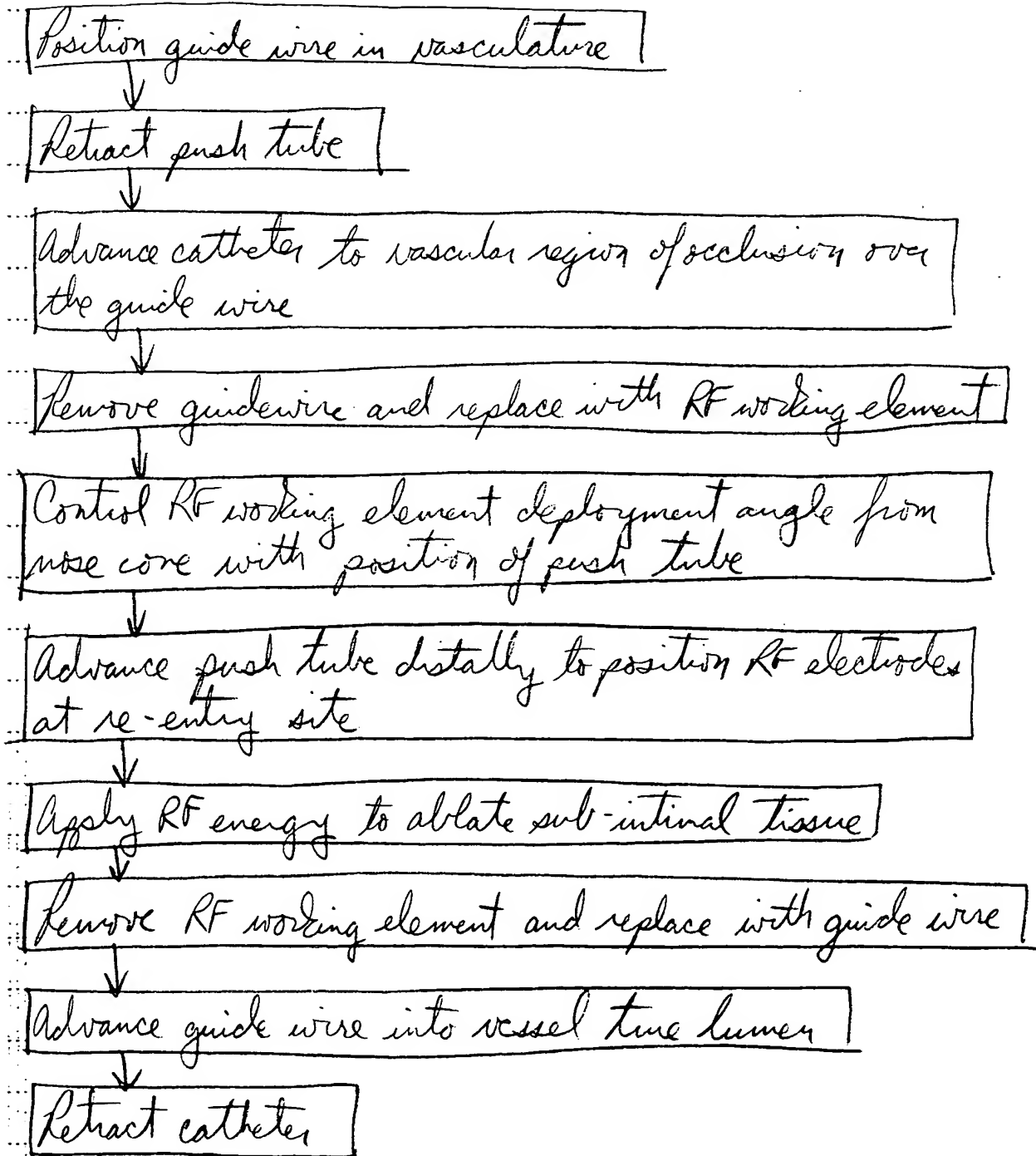


FIGURE 45

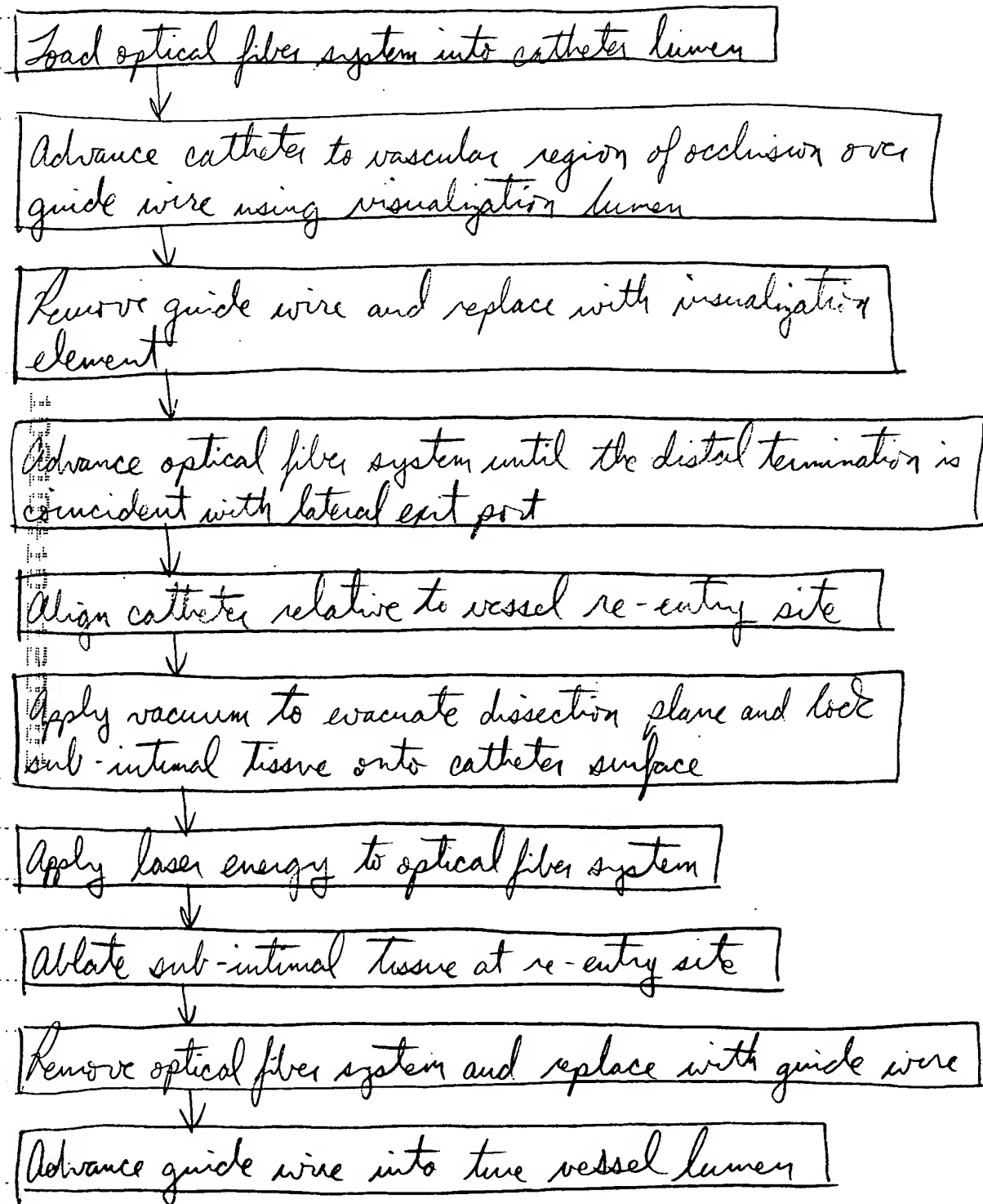


FIGURE 4/6

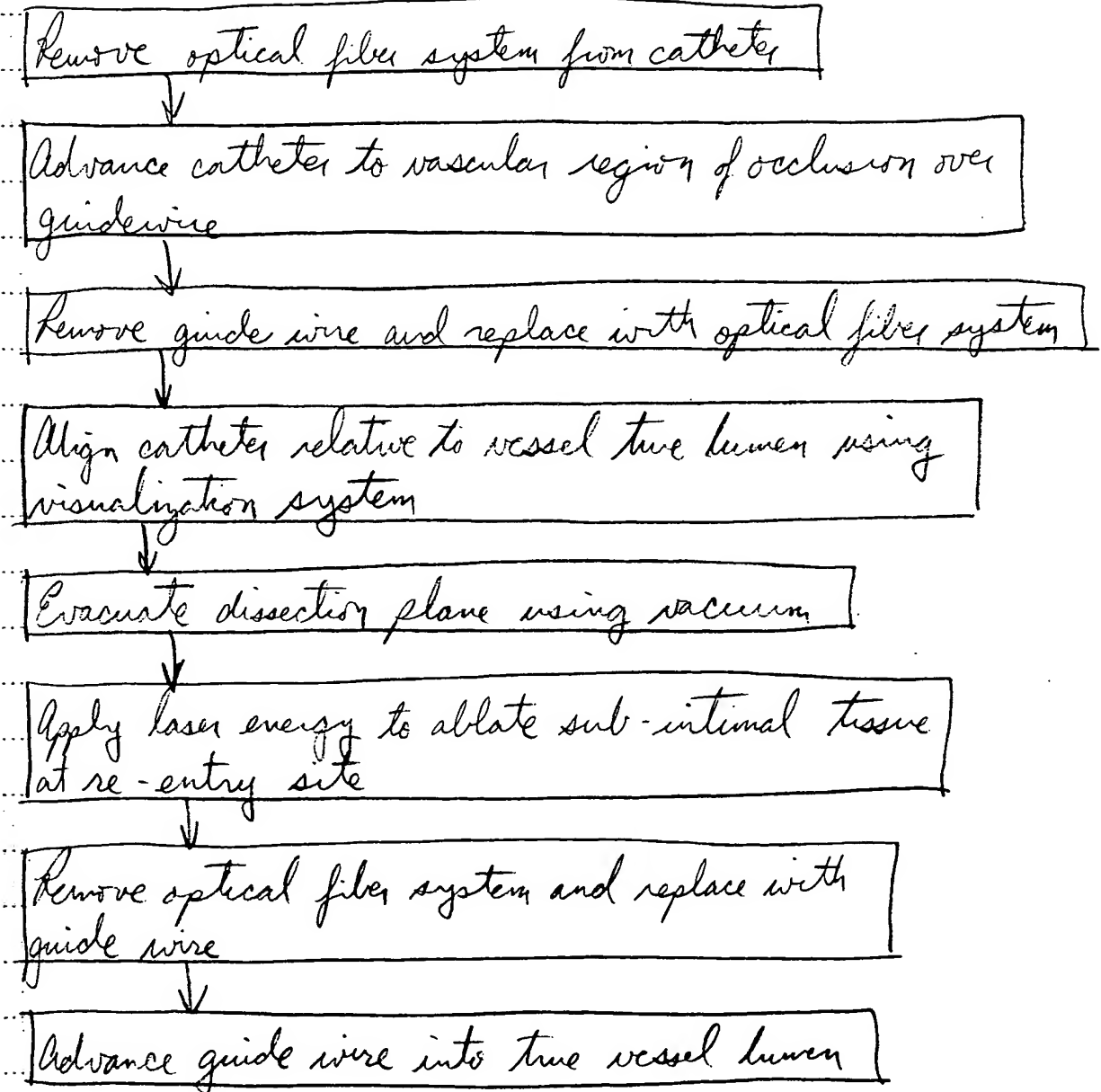


FIGURE 47

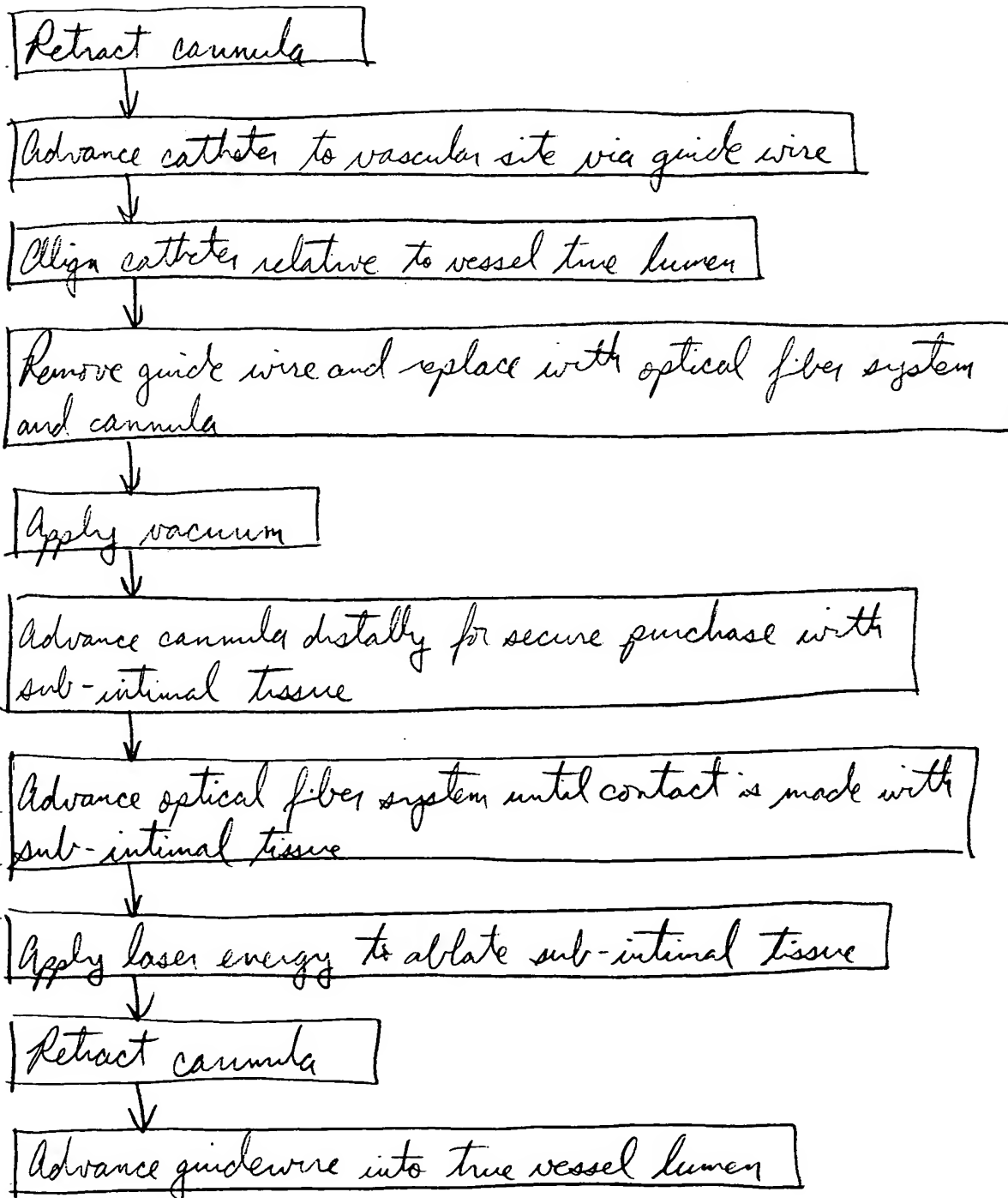


FIGURE 48

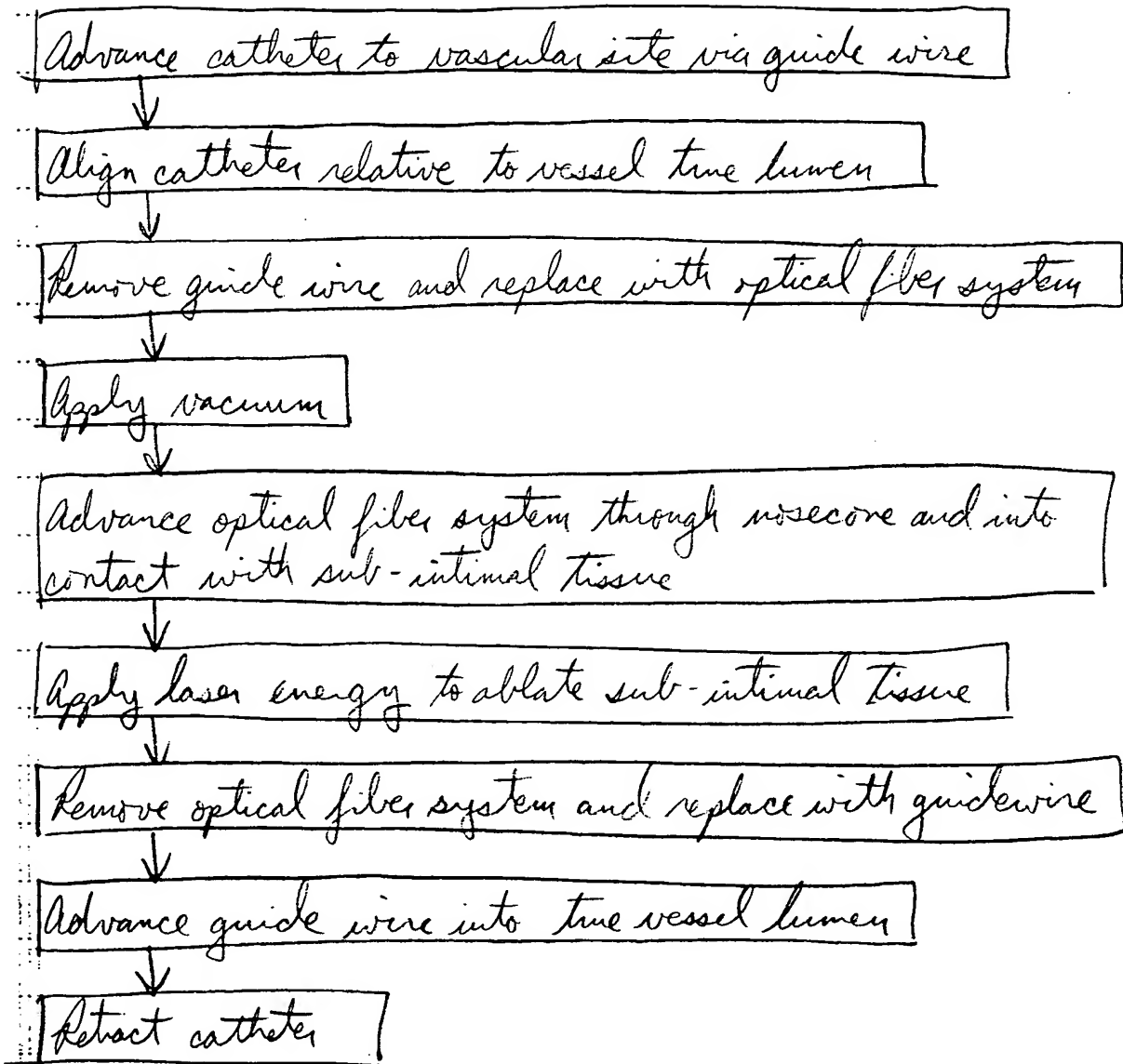


FIGURE 49

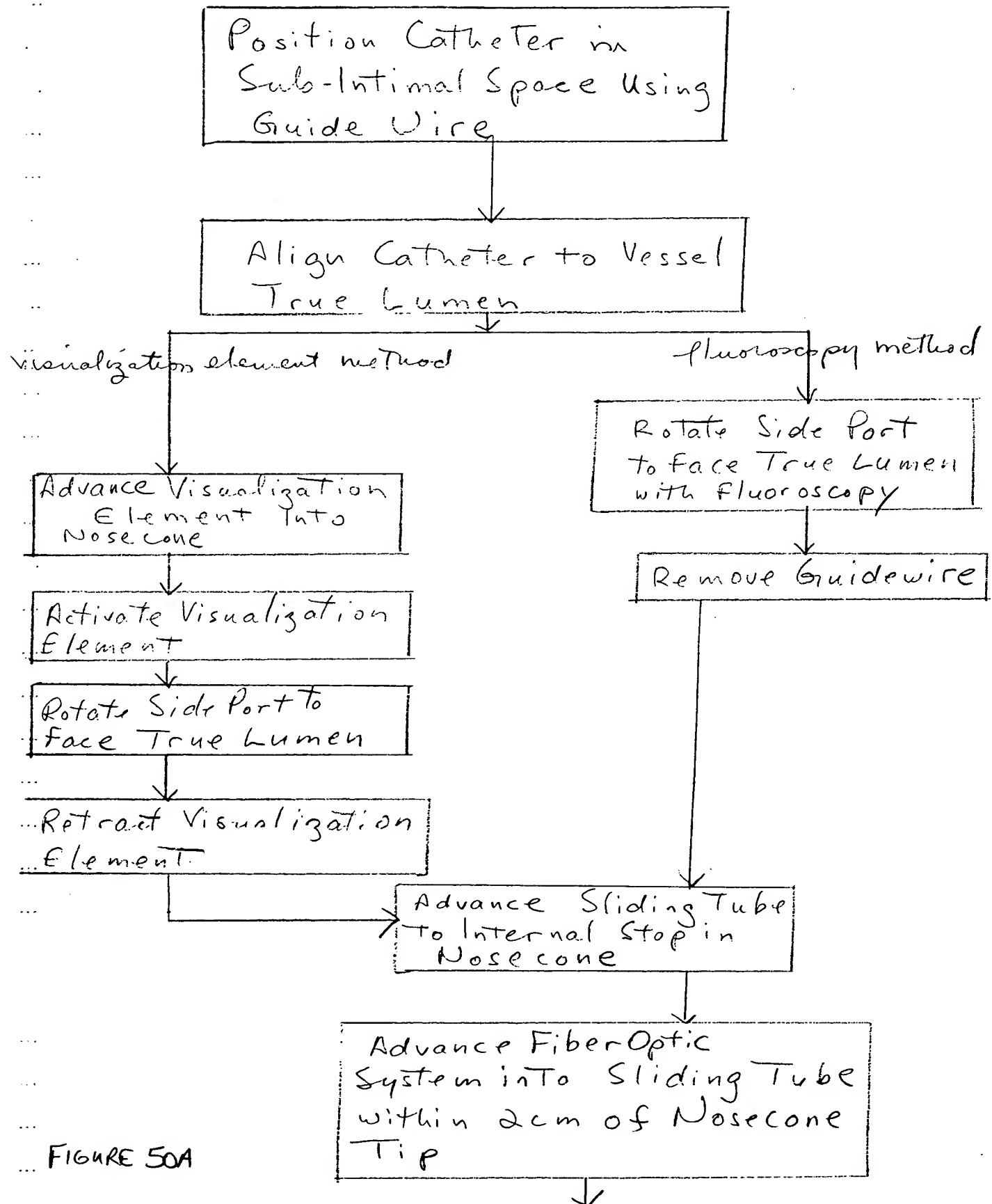


FIGURE 50A

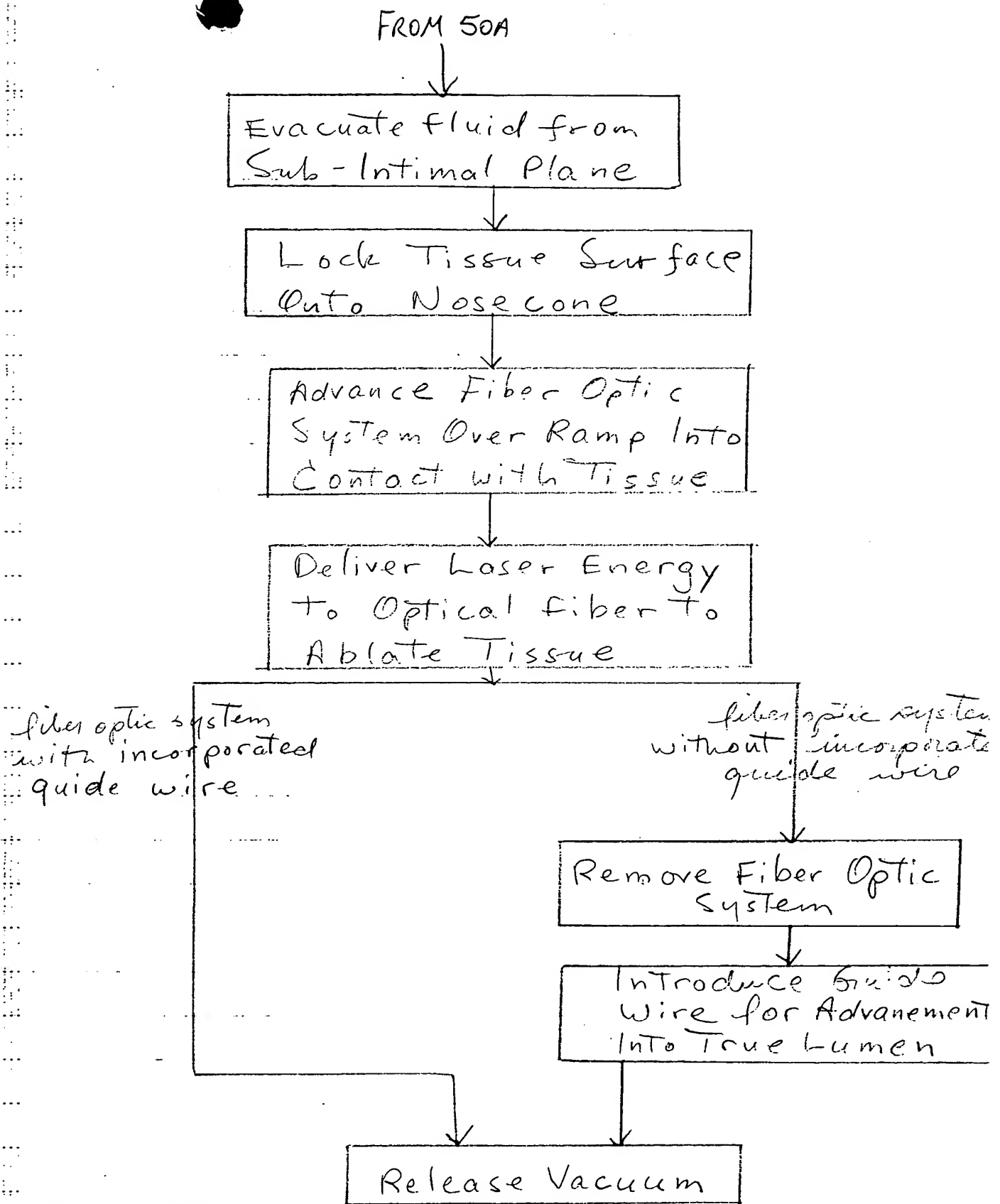


FIGURE 50B

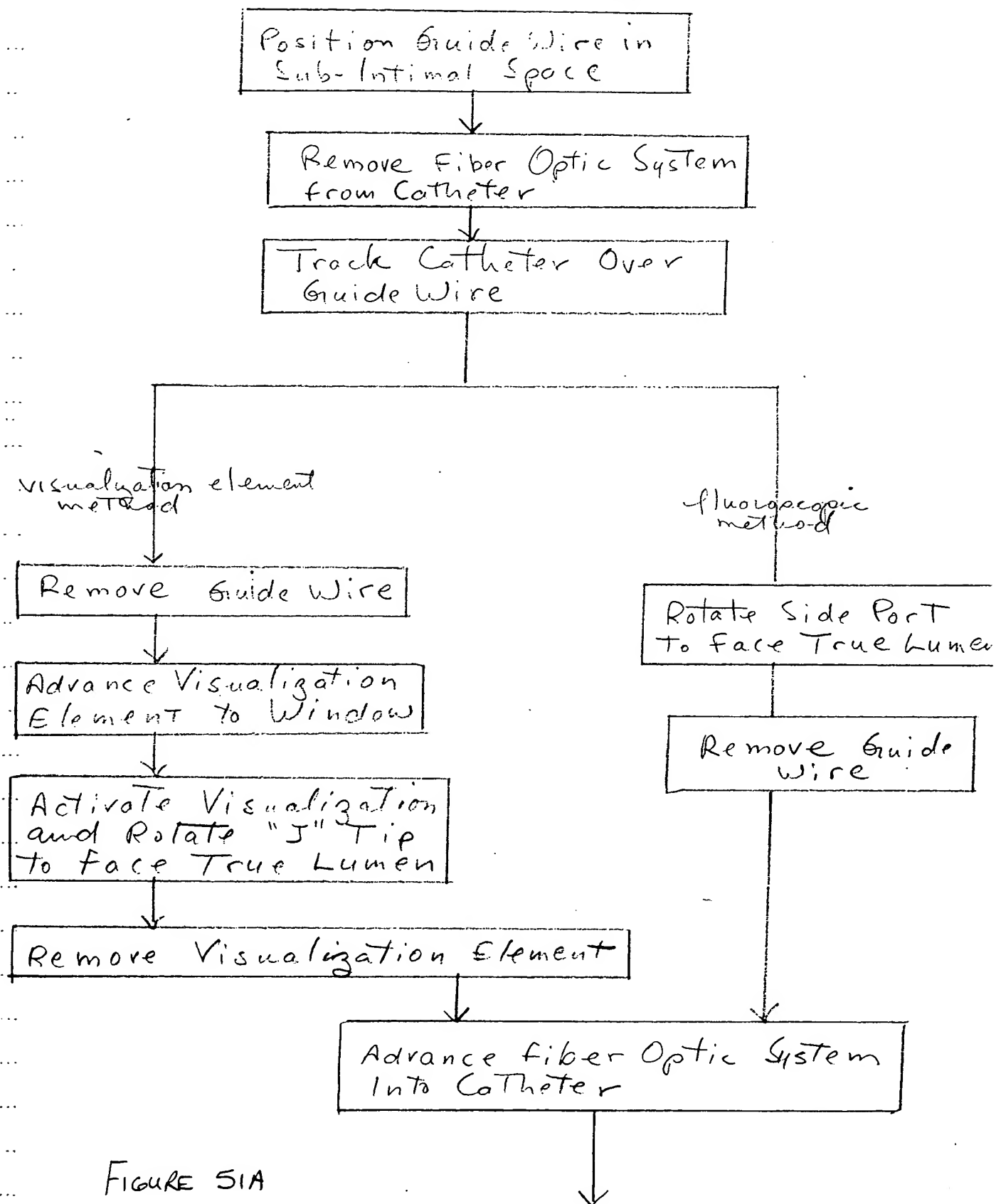


FIGURE 51A

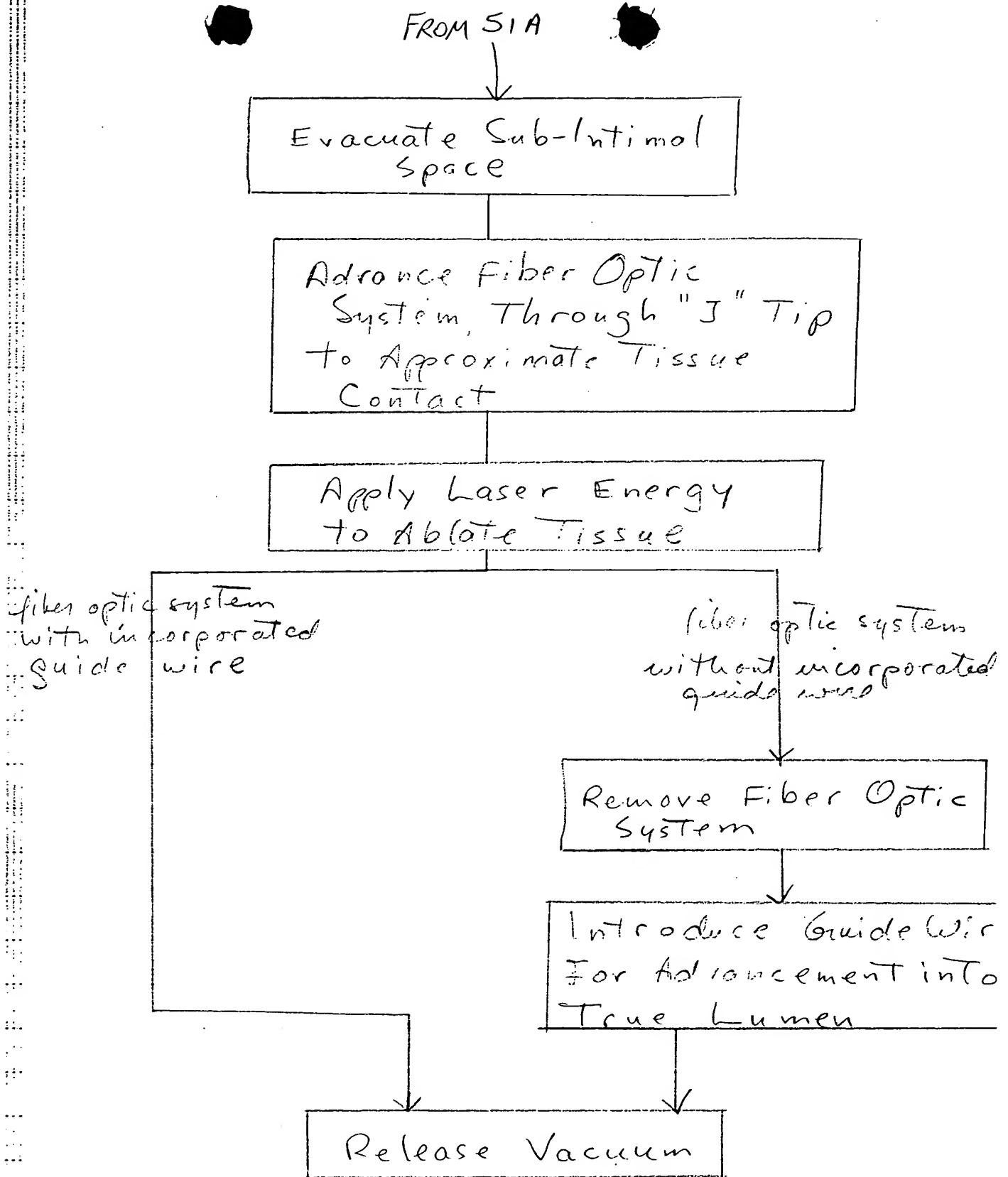


FIGURE 51B

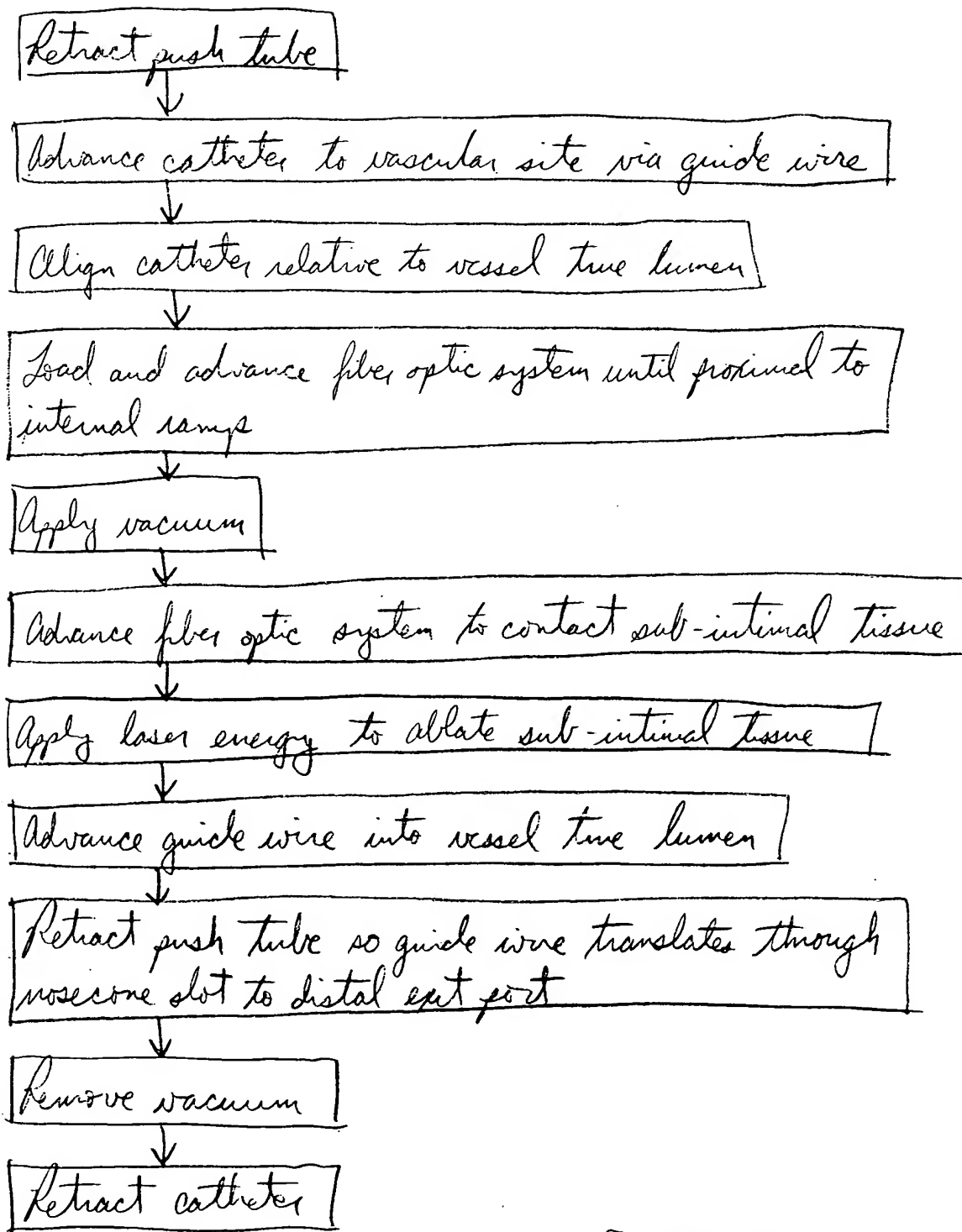


FIGURE 52